MANAGEMENT MANUAL PHES

Integrated Management Manual of PAUL HARTMANN Spain

Document: **MAN-M1.3-01_EN**
Unit/Dept.: **PHES**
Version: 7.0

	Department, Function, Name	Date, signature
Issued by	Q&HSE Engineer, **Jennifer De Leça**	05.05.2022.
Checked by	PHES-RAQ&HSE Director, **Pilar Molina**	05.05.2022
Approved by	PHES-MD, Managing Director **Jordi Guinovart**	05.5.22
Process Owner	PHES - RAQ&HSE Director	---
Training required?	☐ Yes ☒ No **Reason in case of no:** General review of Manual, minor changes which do not require any training. Only communication to the employees is required.	

Change Protocol

Version	Valid from	Reason for change
1.0	01.03.2016	New
2.0	23.03.2018	Changes related to the inclusion of new production unit PHISA (CC17-048) and Changes related to new norms requirements standard UNE-EN ISO 9001:2015; UNE EN ISO 13485:2016 and UNE EN ISO 14001:2015 (CC18-007): Included in Part 1 PAUL HARTMANN IBERIA S.A. (PHISA). New abbreviation definition PHES; Added exclusions of the standards in part Part 2.1; Added Part 2.2 outsourced processes; Part 4.1. Added reference to the Interested parties and Context of the Organization; Part 7.4.1. Enlarged explanation; Added Part 7. 7. Statistics methods; Changed frequency of the Management Review from biannual to annual in different parts of the Manual; Added in part 4.2.1. reference to the Local Process Map in the Annex 5B; Part 5.2. Added reference to the Interested parties and link to new Annex 8 Interested parties.
3.0	11.05.2018	Added New Annex 9: Environmental Management Manual for PHISA (Montornés); Added reference to the new Annex 9 in the part 2. It is added new reviewer of the IMM. Engineering&HSE Manager PHISA .
4.0	30.04.2019	General Update of the Manual following Contents of MAN-M1.3-02_EN PHAG V3 (CC19-014): Added in Part 6.2 non applicable requirements of the standard UNE EN ISO 9001 for the Production unit PHISA; Withdrawn Annexes: Annex 2; Annex 4; Annex 5B and Annex 7; New Annexes: Annex 10; Annex 11; Annex 12; Changed Annex: Annex 1 from “Territorial Scope” to “Regulatory Scope”.

5.0	17.02.2020	CC19-024 Implementation of MDR gaps. Alignment with the Management Manual of PAUL HARTMANN AG V5. All changes are highlighted in blue: Chapter 1: section 2 sentence 2 changed. Section 3 Number of country branches changed from "over 30" to "over 35". Subitem Wound Management "First Aid Sets" changed to "First Aid Plaster Assortments". Subitem "Incontinence hygiene" changed to "Incontinence management" (at 2 positions). Added subitem "Sanimed Group, KOB and CMC". Chapter 2: Section 2 changed *"Quality Policy"* to "*Integrated Policy*". Section 5 changed "*Quality objectives*" to "*Quality & HSE objectives*" and small wording changes. Chapter 4.4.: corrections done, changed PAUL HARTMANN AG to PAUL HARTMANN SPAIN and changed reference Annex 10 to Annex 8.Chapter 5: Updated and in last sentence "…follow the SMART principle,…" deleted and changed "organizational units" by "departments" Chapter 6.1: Changed reference to norms from "UNE EN ISO…" to "ISO …". Changed OHSAS 18001 to ISO 45001. Last sentence revised. Included enumeration with the regulations of products placed in the market by PHAG, including MDR and complemented in LHSA acting as legal manufacturer "and in future according to European Regulation 2017/745 (MDR)". Chapter 6.2: "UNE EN ISO 13485" replaced by "ISO 13485" and "active implants" replaced by "implantable medical devices". Second sentence regarding "custom-made devices according to MDR" added. "UNE EN ISO 9001" replaced by "ISO 9001" Chapter 6.3: Added in first sentence "health and safety and environment" and "Corporate Standard CS-M3.1-99 Glossary" plus two text passages added. Chapter 7.1: Headline expanded and text plus image added to "Process House". Chapter 7.3: "C2.1 ...", "M1.5 ..." and "M2.4 ..." added, SOP image deleted. Chapter 7.4: Updated and for "SOP-C4.1-01a ..." Title adjusted and added relevant outsourced processes for PHISA. Chapter 8.1.1: Added reference to "CP-M1.2-01 Continuous improvement process" Chapter 8.1.2: Added reference to chapters 9.2. Chapter 8.2.1: Heading expanded and sections 2 and 3 added. Chapter 8.2.2: "the CEO blog" replaced by "publishing" plus section 2 editorially amended. Chapter 8.2.3: Completely revised. Chapter 8.2.4: Section 5 "private network" changed to "network".

		Chapter 8.3: First item in enumeration added. Chapter 8.4.1: Document pyramid revised, "CP-M3.1-01 Control of Documents and Records and" added (2x). Chapter 8.4.2: CP-M3.1-01, SOP-M3.1-01a, CP-M5.5-03 and CP-M5.5-04 added. Chapter 8.5: „…, 9.2 and 9.3“added. Chapter 9.2: Third (for PLM) and fourth section (for MDM/UDI) added. Chapter 10.2: Completely revised. Chapter 10.4: Deleted reference to the Annex 9 (withdrawn) Chapter 10.8: Added. Chapter 11: Annex 9 withdrawn
6.0	15.04.2021	**CC20-025** Alignment with the Management Manual of PAUL HARTMANN AG V6. All changes are highlighted in blue: HARTMANN logo updated in this record version due to recent re-launch of HARTMANN brand, template used is not yet formally up-dated with new HARTMANN logo. Chapter 3.1, 3.2 and 3.3 revised. Chapter 6.1: “in future” reference for manufacturing according MDR deleted. Integration of description of the roles inside the PAUL HARTMANN SPAIN structure. Chapter 6.2: Review of the not applicable requirements for all the sites. Separation of the information for PHISA. Chapter 7.1: Image of “Process House” updated. Chapters 8.2.2 and 8.2.4: Adjustments in the forms of communication implemented. Chapter 8.2.3: “dealers” replaced by “distributor”. Chapter 8.2.4.: Updated title of local document SOP-M2.4-01a PHES “Qualification and Training” Chapter 8.4.1.: Updated title and indication of local document SOP-M3.1-01a “Documentation and Records Management” Chapter 4.9) Chapter 8.4.2.: Updated title of local document SOP-M3.1-01a “Documentation and Records Management” Chapter 9.2: CP-C2.1-02 “Material Master Data Management” and CP-C2.1-04 “Unique Device Identification” added. Chapter 10.8: Completely revised. Chapter 11: Integration of Annex 13 (No new Annex, annex already included in Annex 0, not integrated in the Manual).

7.0	20.05.2022	**CC21-112** General alignment with the Management Manual of PAUL HARTMANN AG V7. Included references to BIC Process Design. All changes are highlighted in blue: Chapter 1: General Update of presentation and portfolio. Eliminated reference to feminine products for PHISA. Chapter 2 and 5: Included reference to Corporate Policy. Chapter 3: General update of vision, purpose, and strategy. Chapter 6.1.: Eliminated reference to feminine products for PHISA. Included additional indications for LHSA role. Included Cosmetics and Food complements as products placed in the market by LHSA. Chapter 6.2.: Eliminated reference of P&G activities for PHISA. Chapter 6.3.:Deleted reference to CS and included business processes as well as to Annex 13. Chapter 7.1.: Adapted description due to current Process House implementation and updated picture of HARTMANN Process House. Chapter 7.3.:Deleted reference to CS and included business processes. Chapter 7.4.: Updated corporate process reference. Chapter 8.3.: Included one additional indication of the IMS safeguard. Chapter 8.4.1.: Document Pyramid updated. Inclusion of local Documentation process reference. Chapter 8.4.2.: Updated Data Protection document reference. Included reference of records storage. Chapter 9.3.: Included information related with DMR and DHR documents Chapter 10.2.: Included information related with Technical Documentation. Chapter 9.5.1.: Reference of no customer ownership for PHSA. Chapter 10.2.: Included reference of Clinical evaluation process. Chapter 11: Included reference to Annex 5 recovered.

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Information per e-Mail to:

- CODIR PAUL HARTMANN Spain
- Leadership Team PAUL HARTMANN Spain
- Quality; Regulatory and HSE Department of PAUL HARTMANN Spain

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1. Presentation of the Company

PAUL HARTMANN SPAIN belongs to the HARTMANN Group, one of the leading European providers of professional medical and care products and associated services. Every day, healthcare professionals and patients rely on HARTMANN brands in the core segments of Incontinence Management (e. g. MoliCare®), Wound Management (e. g. Zetuvit®) and Infection Prevention (e. g. Sterillium®). This is expressed in our brand promise of "Helps. Cares. Protects.". With branches in over 35 countries, we are represented worldwide, and our network of distributors enables us to provide our products in around 100 countries.

The focus of the medical ranges is on the provision of systems for professional users in hospitals, doctors' practices, pharmacies, care for the elderly and nursing homes, as well as products for home care. HARTMANN's portfolio is based on in-depth medical knowledge, many years of experience and a profound understanding of different customers' needs, demands and workflows. In order to guarantee the comprehensive and affordable provision of care using medical and care products, HARTMANN works increasingly closely with public health authorities and other entities responsible for funding the healthcare system and with the specialist medical trade and pharmacies. In addition to its medical product ranges for professional target groups, HARTMANN also produces medical and healthcare ranges for end users. They are primarily distributed through dispensing and non-dispensing pharmacies, specialist suppliers of medical products and online channels. In this way, HARTMANN recognizes the increased significance of the market for direct payers.

We ensure the safety of patients, users and the environment and enhance their health and well-being. We also feel obliged to protect the environment, and for all these reasons we fulfil many worldwide requirements.

Three legal entities in PAUL HARTMANN SPAIN: PAUL HARTMANN S.A., LABORATORIOS HARTMANN S.A. and PAUL HARTMANN IBERIA S.A. The facilities are located for the first two in the south of Mataró, Pla d'en Boet II Industrial Estate, Carrasco i Formiguera, nº 48, 08302 Mataró (Barcelona), and for the third in the Industrial Estate El Raiguer (08170) Montornés del Vallés (Barcelona) and that develop the following activities:

• PAUL HARTMANN S.A. (PHSA): manufacturing and development center of medical devices (Woundplasters and tapes). Our main customers are all the HARTMANN Group plants.

• LABORATORIOS HARTMANN S.A. (LHSA): design, commercialization, and distribution in Spain of medical devices, intact skin antiseptics, cosmetics, food supplements, hygiene and consumer products and medicines for human use manufactured by the different HARTMANN Group plants. Our main clients are Pharmacies, Hospitals, Residences and Primary and Home Care in Spain. In addition, we also offer OTC products for the final consumer that are sold in pharmacies and health products establishments. Our focus is on products and services for professional users in hospitals, doctors' offices, nursing homes and home care services.

• PAUL HARTMANN IBERIA S.A. (PHISA): manufacture of medical devices (incontinence absorbers). Our main clients are Pharmacies, Hospitals and Residences in Spain and Portugal, for incontinence products. The development is under the responsibility of PAUL HARTMANN AG (PHAG).

Product portfolio HARTMANN Group

Our products and services are designed for healthcare providers and therefore for hospitals, private medical practices, nursing institutions and mobile care services.

In addition, we provide products for end users, distributed via pharmacies/dispensing chemists and medical specialized trades.

In the **Wound Management segment**, HARTMANN concentrates on solutions for wound treatment and dressings. HARTMANN offers a wide range of traditional and modern wound dressings. The latter include, among other things, the established HydroTherapy treatment concept with the two products HydroClean® and HydroTac® as well as the super-absorbent gauze pad Zetuvit® Plus Silicone Border. In the area of traditional wound management, HARTMANN is a market leader in Europe.

In the **Incontinence Management segment**, the focus is on absorbent products for different levels of incontinence designed to be worn next to the skin. These include the MoliCare® Pants and MoliCare® Elastic product categories. This segment also includes products for patient hygiene and medical-grade skin care.

The **Infection Management segment** encompasses the Risk Prevention and Disinfection divisions. In Risk Prevention, the Company manufactures tailored, pre-assembled component sets, surgical gowns, and drapes for the OR area and examination gloves. In the Disinfection segment, HARTMANN develops and manufactures products for hand and surface disinfection to protect against infectious diseases. This includes the disinfectant Sterillium®, which has repeatedly been named the brand of the century. Sterillium® Protect & Care is also available to end users. During the coronavirus pandemic, HARTMANN plays a major role in the Infection Management segment thanks to the composition of its product and solutions portfolio.

The **Other Group Activities segment** covers the businesses of Group members KNEIPP, CMC and KOB. The KNEIPP Group sells body care products, dietary supplements and herbal medicines under the brand slogan "KNEIPP Works. Naturally." Retail brands in the fields of cotton/cosmetic, medical, baby and home care are mainly promoted via the CMC Group. The KOB Group is an expert in medical textiles and bandages.

We always strive for the highest quality level of our products and of the associated health services, to guarantee the best possible product safety. All regulatory requirements are met.

2. Management declaration

We declare that effective and integrated process management belongs to the main company objectives of PAUL HARTMANN SPAIN and promote a process-oriented approach from the highest level, as well as risk-based thinking throughout the company.

Risk-based process management and its continuous review is an integral part of the company policy and is indispensable for the success of the company. *Quality and Health Safety & Environmental management* (from now on *Integrated Management*) is intended to support process optimization and the long-term company objectives – growth – revenue – independence. The Integrated local policy (see Annex 3 “Integrated policy”) clarifies this goal and is fundamentally based on the HARTMANN Quality Policy (See MAN-M1.3-01 Annex 3 “*Quality policy*”).

It is intended that integrated management will be further developed throughout the company to improve not only product quality, safe work conditions and environmental impact but also the effectiveness of the business processes as well as of all services of the company. Such a management system is intended to forestall

business risks and to contribute to the success of the company. We therefore accept the responsibility for the future of the company and for the expectations of our customers, shareholders, suppliers, employees, as well as those of the authorities and of the public.

We expect that all employees will assist in the changeover of the management system and will work together to implement it consistently. Managers and employees are encouraged to make suggestions for improvements towards further development. They should support the management representatives in their task.

The responsible people at all organizational levels ensure that quality, health and safety and environment (HSE) objectives are introduced and fulfilled, that adequate resources are available and that all aspects of the integrated policy are always implemented at all times. The top management conducts regular management reviews to ensure continuous effectiveness and appropriateness of the Integrated Management System. Certification in accordance with the medical device standards and the European regulations is a condition for all companies that produce medical devices for PAUL HARTMANN SPAIN.

3. Vision, purpose, and strategy

3.1. Our vision

We are the leader in our key segments.

Our corporate vision is based on a solid system of values.

As a high performance, customer-oriented, passionate team we can gain leading positions in our markets.

- **High Performance**
  We are ambitious to outperform the competition, to speed up profitable growth by taking fact-based decisions with a LEAN mindset.

- **Customer-oriented**
  We have the customer at the heart of everything we do, continuously striving to meet and exceed customer expectations, to become the preferred partner of choice.

- **Passionate Team**
  We are ONE strong team, trusting, supporting, and encouraging each other, working at eye-level passionately towards the common goal

3.2. Our purpose

We improve outcomes for professionals, caregivers, and patients.

3.3. Our strategy

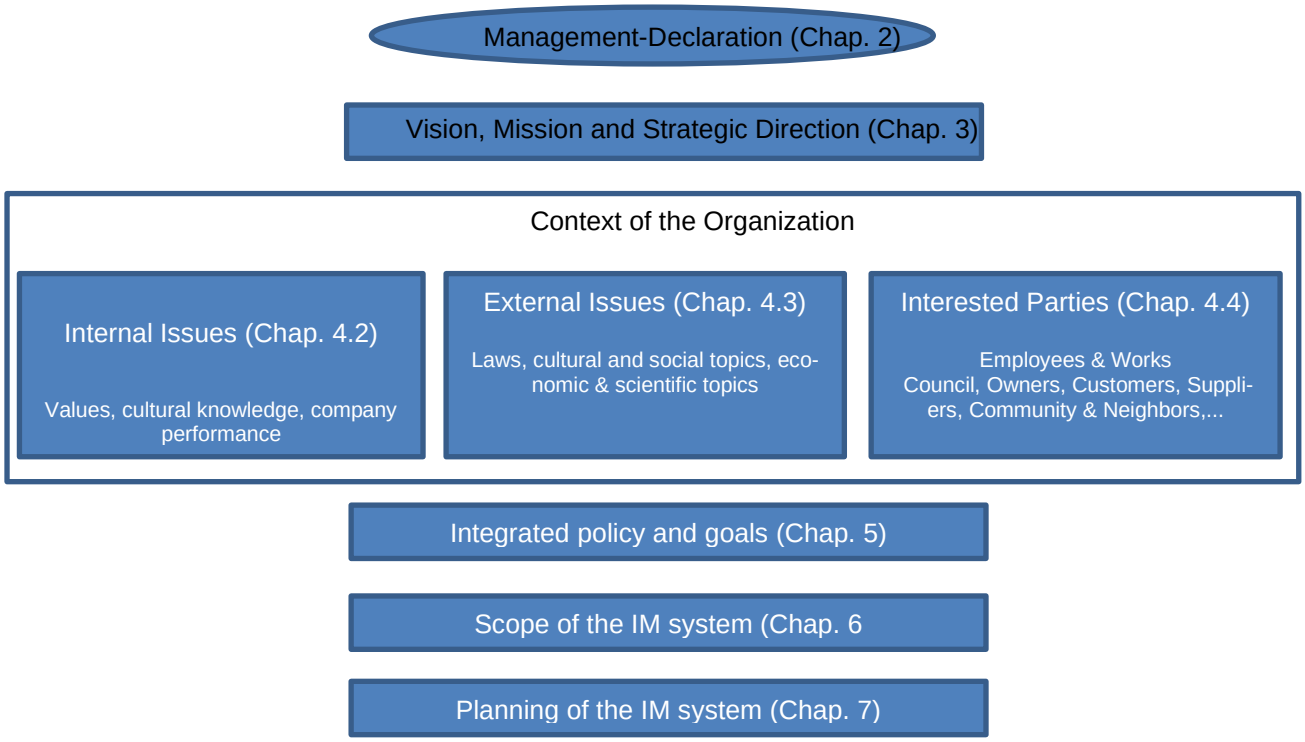
In 2019, HARTMANN launched its transformation program with a planning horizon of five years. With it, the Company intends to achieve a market-leading position in its core segments across Europe, and to establish itself as an even stronger partner in healthcare markets.

The program uses a multitude of measures to address four strategic levers:

- growth through an increased rate of innovation;
- the development of digital business models;
- a greater focus on core business areas in attractive market segments;
- and an improved costs position across the entire value chain.

4. Context of the organization

4.1. Overview



With the aid of internal and external issues, including the interested parties, this management manual aims to establish the context of the organization.

4.2. Internal issues

The internal topics relevant to our strategy and the mission behind our company are based on our values, knowledge of culture and our company performance. More details are developed in Local WI Risk & Opportunities.

4.3. External issues

External topics have a significant impact on the development of our company and our ability to achieve our company goals. More details are developed in Local WI Risk & Opportunities.

One major external topic, compliance with national and international legislation, is also covered in Annex 1 “Regulatory scope”.

4.4. Interested parties

As a partner to its customers, PAUL HARTMANN SPAIN develops and manufactures the products and services listed in the product portfolio (see Chapter 1). Customer expectations from the market, especially from identified interested parties, are incorporated into the product design as well as manufacturing and service processes. The interdependence and interaction with interested parties is described in Annex 8 “Interested parties” by naming the relevant processes and is implemented via the risk-based approach of the quality management system (see also Chapter 7.2).

5. Integrated policy and goals

The integrated policy of PAUL HARTMANN SPAIN is defined by the top management in connection with management reviews and is also checked for continued applicability as well as adapted. The Integrated Policy is defined based in the HARTMANN Quality Policy (See MAN-M1.3-01 Annex 3 “*Quality policy*”). That is why HARTMANN Spain quality policy refers to the translation of to the Global Quality Policy but is adapted to complement and cover also HSE system topics, not included in the Global document.

The integrated policy is approved by the Managing Director (see Annex 3 “Integrated Policy”) and communicated to the entire organization.
In parallel with the integrated policy, the objectives are adopted, checked, and revised if necessary, by the top management in the management review. These objectives are communicated within the organization and are broken down into process objectives within the departments, which are then followed up and communicated to top management.

6. Scope of application for the IM system

6.1. Purpose and scope

In principle, the PAUL HARTMANN SPAIN Integrated Management System (IMS) follows the requirements of the principal norms ISO 13485; ISO 9001; ISO 14001 and ISO 45001 considering the requirements listed in Annex 1 “Regulatory scope”.
This manual describes the structure and the primary processes of the IMS of PAUL HARTMANN SPAIN within the three companies: LHSA, PHSA and PHISA. It also describes the organizational structure with the main positions of responsibility.

An overview of all valid processes can be found in MAN-M1.3-01_Annex 6 “Process List”.

In Terms of roles in accordance with European Regulation (EU) 2017/745 (MDR), PAUL HARTMANN SPAIN has the following structure:

- LABORATORIOS HARTMANN S.A. (LHSA) acts according to the following roles:
  - ‘Manufacturer’ means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark.

- 'Importer' means any natural or legal person established within the Union that places a device from a third country on the Union market.
- 'Distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.
- 'Exporter' means any natural or legal person established within the Union that places a device in a third country outside the Union market.

The devices of the HARTMANN Group placed in the market by Laboratorios HARTMANN SA are:

- Medical devices as manufacturer according to European Directive 93/42/EEC (MDD),
- Medical devices as manufacturer according to European Regulation 2017/745 (MDR),
- Biocides according Regulation EU 528/2
- Cosmetics
- Food complements

which are marketed under the following address:
PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim, Germany
Tel: +49 (0)7321 36-0
Fax: + 49 (0)7321 36-3636
49 (0)7321 36-3636
Email: info@hartmann.info
Internet: www.hartmann.info

LABORATORIOS HARTMANN S.A. is also legal manufacturer under European Directive 93/42/EEC and according to European Regulation 2017/745 (MDR) for some medical device's ranges distributed in Spain. These products are marketed under the following address:

LABORATORIOS HARTMANN SA
Carrasco i Formiguera, 48
08302 Mataró, España
Tel: +34 937417100
Fax: + 34 937417111
Email: info@hartmann.info
Internet: www.hartmann.info

In addition, to the role of legal manufacturer, importer, exporter, and distributor of medical devices, LABORATORIOS HARTMANN SA also has the following licenses:

- License of Medical Devices (Manufacturing, Warehousing, Distribution, and Importer)
- License of Biocide (Warehousing and Distribution)
- License of Drugs (Market holder)

- PAUL HARTMANN S.A. (PHSA) is a production plant of medical devices for third legal manufactures.
- PAUL HARTMANN IBERIA S.A. (PHISA) is a production plant of medical devices for third legal manufactures (incontinence absorbers).

6.2. Requirements of standards not applicable

In principle, the QMS of PAUL HARTMANN SPAIN follows the requirements of the controlling standard **ISO 13485.**

Not applicable are the following requirements for LHSA and PHSA (Mataró):

- Requirements for implantable medical devices (7.5.9.2) as these do not belong to the product or services portfolio of PAUL HARTMANN Spain.
- Requirements for Activities during the installation (7.5.3) since the manufactured medical devices are in most of the cases single use products or products to be applied on patients and do not require any installation.
- Specifically for the production unit PHSA, requirements for cleaning of the products (7.5.2) since the manufactured medical devices are in most of the cases single use products or products to be applied on patients and do not require any specific requirements for cleanliness of the product.
- Specifically, for the production unit PHSA, requirements for Technical Service Activities (7.5.4) since the manufactured medical devices are in most of the cases single use products or products to be applied on patients and do not require Technical service.

All standard chapters are applicable from ISO 9001 for LHSA and PHSA.

Regarding standard chapters not applicable from ISO 9001 and ISO 13485 specifically related to PHISA (Montornés), the following requirements have the below mentioned total or partial exclusions:

- Requirements on Planning and Operational Control (7.1 – 13485; 8.1 – 9001).
- Requirements on Design & Development (7.3 – 13485; 8.3 – 9001). Total exclusion since the Development department for HARTMANN products is managed by PHAG.
- Requirements on Procurement/Process Control, products, and services (7.4 – 13485; 8.4 - 9001). Partial exclusion since the procurement management of the raw and pack materials for HARTMANN products is managed by PHAG.
- Requirements on 7.5.2 – 13485. Total exclusion since there are no cleaning activities for products.
- Requirements on 7.5.3 – 13485. Total exclusion since there are no installation activities for MDs.
- Requirements on 7.5.4 – 13485. Total exclusion since there are no technical assistance for MDs.
- Requirements on 7.5.5, 7.5.7 both from 13485. Total exclusion since there are no sterile products activities in the site.
- Requirements on 7.5.9.2 – 13485. Total exclusion since there are no implantable in the site.

According to (EU) 2017/745 (MDR) “custom made devices” not applicable, also not part of the product portfolio of PAUL HARTMANN Spain.

6.3. Management System (Q&HSEMS) and Manual (MAN)

This management manual and further quality, health and safety and environment documents that are also applicable (see Chapter 8.4) cover the scope of the IMS of PAUL HARTMANN SPAIN as described in Chapter 6.1 of this manual.
Further-reaching regulations down to the process and sub-process level can be found in the “Glossary”, business processes, CPs (corporate processes), SOPs (standard operating procedures) and WIs (working instructions). The controlling documents can be found in MAN-M1.3-01 Annex 6A / Annex 6B “Process List”.
A description of the process interfaces and dependences can be found firstly in the individual process descriptions and also in the MAN-M1.3-01 Annex 13 “Interaction Matrix”.

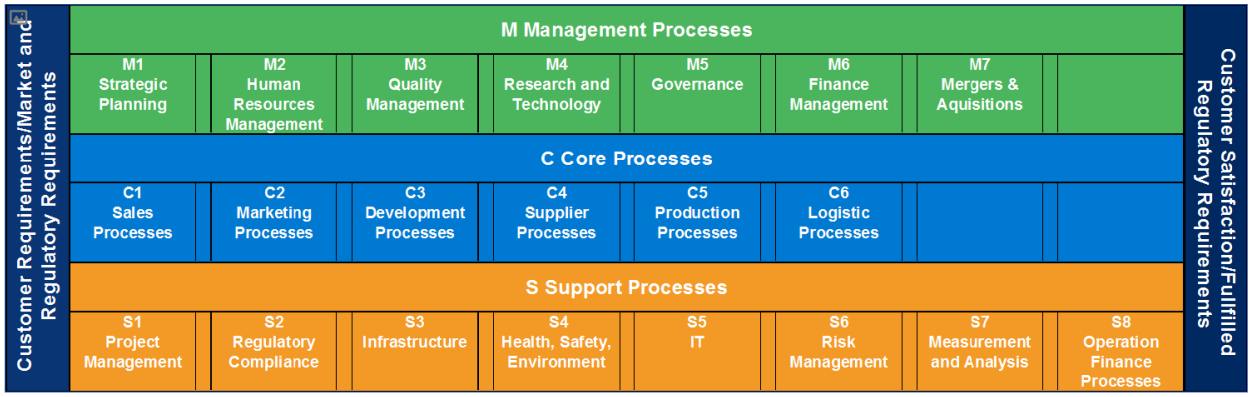
7. Planning of IM system

The top management will ensure the planning and proper functioning of the integrated management system in case of changes. As such, the IMS of PAUL HARTMANN Spain contains at all times all of the processes necessary for conducting the business. Potential risks from the system or the boundary conditions about the furnishing of services are considered once a year in the management review and are also analyzed by Risk Management throughout the year (see Chapter 10.6) and reported appropriately to management. Based on this information, corrective and preventive actions are initiated wherever necessary (see Chapter 8.4.3) and also as part of the continuous improvement process (see Chapter 8.1.1).
Furthermore, there is also an internal risk reduction management system that helps to recognize all risks that are of significance to HARTMANN in good time and to adopt the relevant measures. The opportunity and risk-based future analyses are also incorporated into the strategy. This comprehensive analysis of potential sources of risk strengthens the risk awareness of the entire organization. Preventive measures are very important because they may be able to strengthen potential weak spots. Recording opportunities and risks is done throughout the Group via standardized risk management software, which is used by the entire organization.
Opportunities for improvements in business processes are recorded in IMS quality requests and in the IMS quality request list.
At the production level, there is a discrepancy analysis that compares current situations and problems with the ideal case scenario and defines the relevant measures. Cause analyses also result in opportunities for preventing possible problems over the long term.

7.1. Integrated Management System and HARTMANN Process House

The integrated management system (IMS) of PAUL HARTMANN Spain has a process-oriented structure. The underlying processes are subject to ongoing monitoring and thus improvement processes. The structure is designed for applicability, growth, sustainability and independence of the company and its processes.

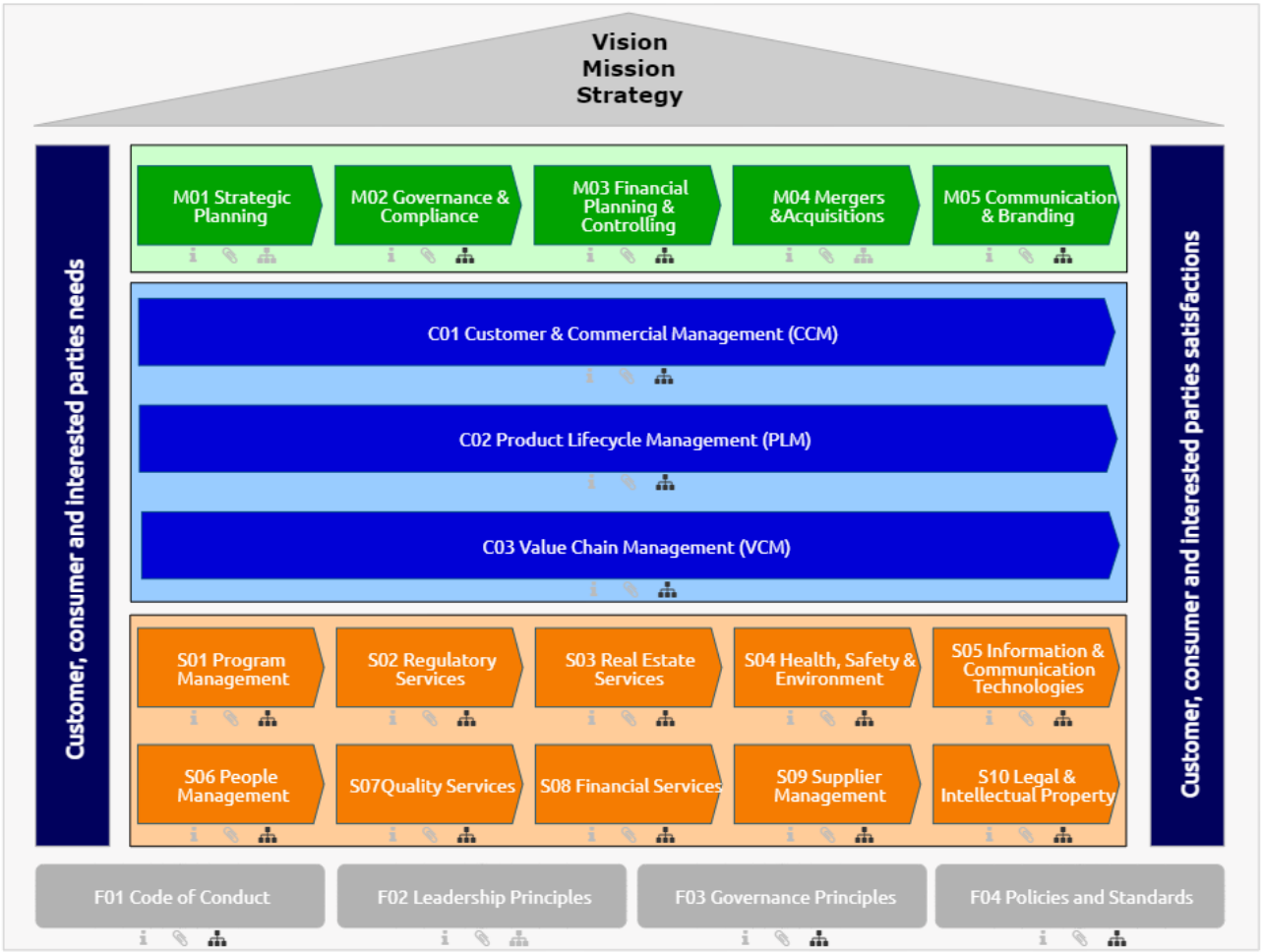
The process-oriented structure of the IMS is reflected in the organizational structure of the MAN-M1.3-01 Annex 5 “Process Map”) and summarized here



The complete overview of all CPs; SOPs; WIs applicable to PHES are listed in MAN-M1.3-01_Annex 6A/Annex 6B “Process List”.

The following picture shows the new HARTMANN “Process House” already implemented in Corporate Level in the BIC Process Design System and for future implementation in HARTMANN Spain with its 18 Processes:

- 5 Management processes: M01-M05
- 3 Core processes: C01-C03
- 10 Support processed: S01-S10

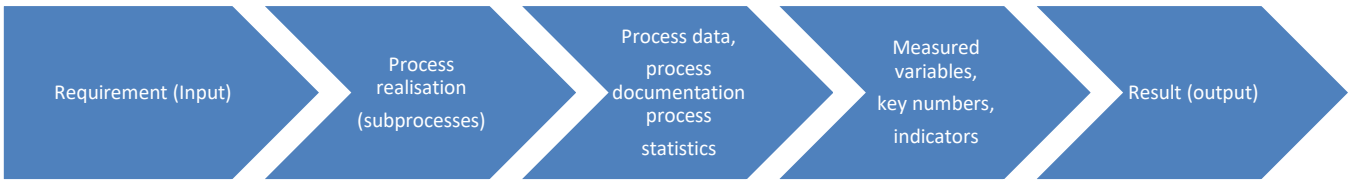


7.2. Risk-based approach

As already presented in Chapter 4.4 of this manual, an organization such as PAUL HARTMANN SPAIN is involved in lots of interrelationships and interactions with both internal and external partners. This may lead to dangers for the interested parties (see Chapter 4.4) and may thus also jeopardize the company.
For this reason, we pursue a risk-based approach to keep these risks low or to avoid them completely. As a result, we have designed our processes using risk management (see also Chapter 10.6).
The observation of these processes as well as feedback from interested parties are used as part of the management review (see Chapter 8.1), which may result in revisions to process risk management of business processes as part of the ongoing improvement process.
Additional to this, the risk-based approach of the processes is also part of the Local WI Risk & Opportunities.

7.3. Process-oriented representation

The basic representation of the processes always follows one and the same principle, which is presented in the following figure:



In this context, it is necessary that all employees adhere to the process concepts.

In our integrated management system, there are overarching processes that interact with lots of other processes – see M1.3-01 Annex 6A/Annex 6B "*Process List*". These overarching processes are:

- C2.1 …. (BIC C02)…….. Product Lifecycle Management
- C4.1 …. (BIC S09-01)……. Supplier selection
- M1.5 …. (BIC M02-05)……. Group Reporting
- M1.6 …. (BIC M02-02)……. Management review
- M2.4 …. (BIC S06-06)……. Qualification Management
- M3.1 …. (BIC M02-03)……. Control of documents and Control of records
- M3.2.1 .. (BIC M02-06)……. Internal audits
- M3.3 …. (BIC M02-05)……. CAPA process
- M3.4 …. (BIC C02-01-08)… Change control management
- S7.3 …. (BIC C03-07)……. Control of non-conforming products

7.4. Outsourced processes

Due to the size of our company, we are not always able to carry out all our tasks within the company itself. This not only applies to manufacturing processes such as sterilization, but also product development, distribution and product and facility maintenance, for which our company relies on external service providers.

Such processes are described as "outsourced processes" and are regulated by our integrated management system in CP-C4.1-01 "Supplier Selection" (BIC: S09-01) and regulated via contractual agreement when required.

The relevant outsourced processes for LHSA are:

- Logistic process
- Sterilization process (Ethylene Oxide)
- Technical Service (Vivano)

The relevant outsourced processes for PHSA are:

- Sterilization process (Ethylene Oxide)
- Logistic process
- Secondary packaging process

The relevant outsourced processes for PHISA are:

- Logistic process

The external services more relevant for PAUL HARTMANN Spain are Cleaning activities; Pest Control; Laundry; Calibrations; Training; Labs, Temporary workers companies and Translations activities.

8. Management processes (M)

8.1. Strategic planning (M1 – BIC: M01)

8.1.1. Continuous improvement

The top management has dedicated itself to the constant improvement of the effectiveness of its IMS and thus also to the constant improvement of its processes. This continuous improvement process is driven by the CAPA process (see Chapter 8.4.3) with participation of all employees. See also CP-M1.2-01 *"Continuous improvement process"* (BIC: M02-07).
The management review is also a major contributing factor to the improvement of the system, as this is where all available data is aggregated, assessed, and subjected to actions.

8.1.2. Customer orientation

The top management of PAUL HARTMANN SPAIN ensures that the wishes of the customers are known within the organization and fulfilled as well as possible. Understanding the customers' wishes is therefore one of the first activities in the product lifecycle management process (see chapter 9.2 and CP-C2.1-01 "*Product Lifecycle Management*" (BIC: C02)), which serves as input for the product development process (see Chapter 9.3).
The alignment of the services and products of PAUL HARTMANN SPAIN with customer expectations is regularly reviewed, e.g., in the distribution and service processes (see Chapter 9.1).

8.2. Human Resources management (M2 - BIC: S06)

Necessary resources for assuring the objectives of the company and of the IMS are defined, planned, and made available where appropriate by top management in the context of the management review.
The company's staff are a major resource and interested party (see Chapter 4.4) and safeguard the future of PAUL HARTMANN SPAIN. Safeguarding this resource is not only the task of knowledge management (see Chapter 8.2.4) but also of our staff loyalty programs (see also Chapter 10.4), which are designed to provide various resources and ensure employee satisfaction.
The responsibilities within the processes are defined in roles. The definition of roles is regulated by SOP-M3.1-01a "Documentation and Records Management" (BIC: M02-03). The top management ensures that the responsibilities and authorizations within PAUL HARTMANN SPAIN are established, documented, and announced via organizational charts and position profiles (POPs).
The rules about substitutes in case of absences are also filed in these organizational charts and in the POPs. If such rules are lacking within a department, the supervisor automatically becomes the substitute in the case of an absent employee.
The recruitment of new staff is also done based on the position profile in question, which serves as the job advertisement or job search profile via recruitment agencies.

8.2.1. Management representative, Safety Officer, responsible people

The management of PAUL HARTMANN SPAIN has designated the roles Quality Management Representative (QMR) and Head of Emergency (JE) as the representative of management. This and the definition of the Safety Officer and his or her deputy are presented in the corresponding processes.

The management of PAUL HARTMANN SPAIN has designated within the organization one “person responsible for regulatory compliance (PRRC)” within the meaning of Article 15 of the MDR. Job descriptions (POPs – Position Profiles) define the tasks of the representatives.

8.2.2. Internal communication

Top management requires a continuous communication process within the entire organization. This is assured via appropriate meetings and above all reporting lines, which are filed in the department-specific organizational charts.
In this way, staff meetings and town hall meetings are defined at a company level, supported by the publishing on the intranet or by CEO and Management Board emails on important topics, such as organizational changes. The management review is also accessible to members of staff via the intranet under SharePoint “*Spain Quality Documentation*”. At the company level, regular meetings are also organized for the employees involved. Other communication channels include our “Intranet – Connect” and our internal social network, “HARTMANN-Yammer”. Local procedures are available for more details in Internal Communication.

8.2.3. External communication

For the different external communication channels (see also chapter 4.4 and 9.1.2) different people / areas are responsible in the PHES under PHAG communication rules. For communication with:

- Authorities: The person responsible for regulatory compliance (PRRC) (see also Chapter 8.2.1), the Safety Officer for Medical Devices and his deputies, e.g., in the case of reportable incidents, and the Regulatory Affairs Department, e.g., about market approvals.
- Notified Bodies: QMR for system-related topics and PRRC for Regulatory Affairs for product-related topics.
- Economic operators: Procurement, our country organizations, and our Global Supply Chain, as well as our sales department contact our economic operators (manufacturers, authorized representatives, importers, distributors and the PHES responsible people).
- Customers: External communication takes place via medical device advisors or via the defined marketing tools such as our company homepage. All information published on products (see Chapter 9.2) originate from the product development process (see Chapter 9.3) and thus correspond to the validated development result.
- Other interested parties: The “Corporate Communication” department is responsible for the design and administration of various communication channels to our interested parties, such as shareholder communication, press & media relations, and sponsoring & donations.

In the event of an unannounced visit by the authorities, notified body, inspectors on any legal area, customers, etc. the procedure is set out in a Local SOP.

8.2.4. Organizational knowledge (internal and external sources)

PAUL HARTMANN SPAIN acquires knowledge about the markets it serves and on changes in these markets. The focus here is on our customers and the users of our medical devices (see Chapter 9.2). Their needs are recorded and used to derive possibilities for guaranteeing the usability of our products.
At the same time, the legal and regulatory requirements of products and services, as well as changes to these, are also observed in the target markets (see Chapter 10.2).
Furthermore, involvement in expert committees (e.g., standardization), associations and the temporary assistance of external experts (advisors) are also sources of knowledge management.

The HARTMANN knowledge management is rounded off with collaborations tools such as SharePoint, Microsoft Teams and Yammer. In addition to social cooperation, these tools also offer employees the opportunity to work together in teams and to stay informed about the work, experiences, and knowledge of their colleagues. This enables us to guarantee the future viability of our products and our company.
When employees leave the company, they share their knowledge with their successor or supervisor so that the knowledge remains accessible to HARTMANN.

Finally, non-disclosure agreements in the employment contracts of all staff prevent the unauthorized sharing of insider knowledge.

The knowledge available is shared internally at PAUL HARTMANN SPAIN by ensuring that each member of staff is qualified in line with the position profiles (see also Chapter 8.2), including the regulatory requirements. This is ensured via the process SOP-M2.4-01a PHES "*Qualification and Training"* (BIC: S06-06). This process also serves to boost the awareness of all staff of actively working together to improve the efficacy of the IMS and to ensure that they are aware of the advantages of improved performance in terms of the market and product. At the same time, it also boosts awareness that non-compliance with guidelines has consequences. This also covers how staff influence product quality and thus also customer satisfaction.

8.3. Quality management (M3 – BIC: M02)

All employees of PAUL HARTMANN SPAIN must consistently support the implementation of the IMS. The top management and all employees must strive for constant improvement of the system (see also Section 8.1.1) and in this way support the tasks of the management representative (QMR, quality management representative). In PAUL HARTMANN Spain, the RAQ&HSE Director is assigned as QMR and PRRC (according MDR) and this function is reporting directly to the Managing Director ensuring the independency and authority to develop and deploy to all the team all quality related topics. Every employee in the organization is encouraged to point out inconsistencies and potential improvements.

Through our IMS we safeguard the following:

- Identification, implementation, and maintenance of the regulatory requirements for the products we develop, produce and/or trade over the entire life cycle, while at the same time taking customer requirements into account,
- Trust of the customers and patients in the quality and usability of our products,
- Improved patient health and greater patient satisfaction thanks to the use of our products,
- Economic process optimization.

Our IMS lays the basis for:

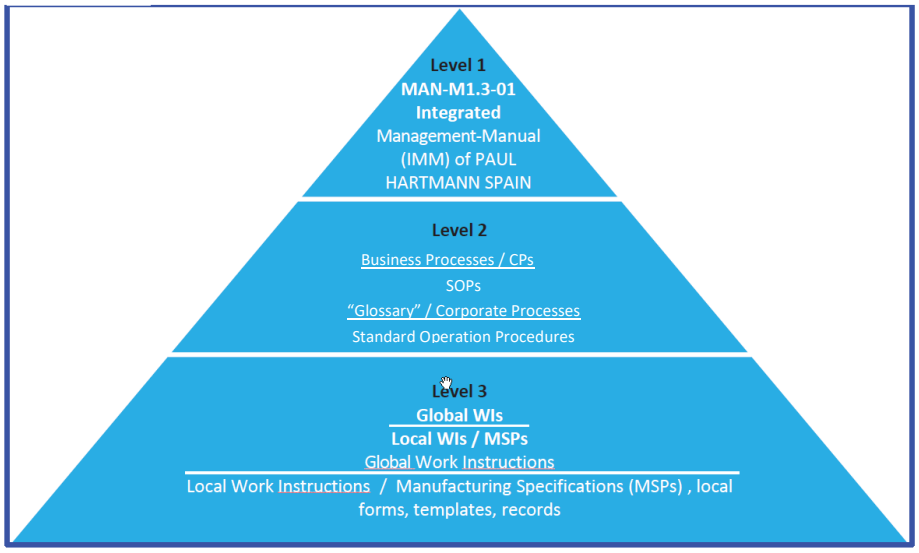
- Identifying all processes and their uniform application necessary for the organization,
- Defining the sequence and interaction of the company processes,
- Establishing the necessary criteria and methods for control and realization of processes,
- Ensuring the availability of necessary resources and information for performance and monitoring of processes
- Ensuring monitoring, measurements, and process analyses,
- Ensuring realization of actions to achieve planned results,

- Assuring process effectiveness and striving for continuous improvement processes,
- Controlling outsourced processes that may influence product compliance or the product specification.

8.4. Documentation requirements

8.4.1. Control of documents

Thanks to the process-oriented documentation of our IMS, this is easy to understand for all employees. The content necessary for the specific employees is illustrated at various documentation levels. The documentation levels defined in HARTMANN Group and therefore for PAUL HARTMANN SPAIN are represented in the following pyramid:



A complete overview of all requirement-related documents applicable to PAUL HARTMANN SPAIN can be found in MAN-M1.3-01 Annex 6A/Annex 6B "*Process List*".
External documents are covered by the regulations in the quality management system at PAUL HARTMANN SPAIN (see CP-M3.1-01 "*Control of documents and records*" (BIC: M02-03), SOP-M3.1-01a "*Documentation and Records Management*" and SOP-M3.1-01b "*Management of External documentation*" *(BIC: M02-03)*). In this way, customer specifications or contracts and industrial standards may apply to our company, products, and services. As is the case for our own documents, these documents are also clearly identified, managed, and archived, thus ensuring proper protection from any environmental influence or unauthorized access.

So that all relevant employees are kept up to date about the latest regulatory requirements in our integrated management system and are also able to implement them to expectations, training will be provided on the relevant processes and their amendments (see CP-M3.1-01 "*Control of documents and records*" and SOP-M3.1-01a "*Documentation and Records Management*" (BIC: M02-03) Chapter 4.9). The efficacy of training measures will also be assessed.

8.4.2. Control of records

The quality and HSE records of PAUL HARTMANN SPAIN show that the IMS and its functioning are complying. Furthermore, these records can be used as proof of compliance with defined process and product specifications in cases pertaining to liability for damages. As a result, ensuring retrievability and archiving is vital for the survival of the company.

The layout, content of the records to be created and the retention methods and duration are defined in the CP-M3.1-01 "*Control of documents and records*" and SOP-M3.1-01a "*Documentation and Records Management*" (BIC: M02-03), thus ensuring proper protection from any environmental influence or unauthorized access.
The product documentation, the Device Master Record (DMR), Design History File (DHF), and the Quality System Record (QSR) to be created are also records in this sense. The Technical Documentation, DHF and DMR documents are stored in TeamCenter database. In place of an internal attributive incoming goods inspection, a review of the supplier's certificate of analysis (CoA) is done instead. These external documents (see also Chapter 8.4.1) are managed as internal records.

The authorization concepts for the main IT systems are defined in the IT processes (see CP-S5.1-02 "*IT system development and maintenance*" (BIC: S05-05)) and includes various levels of authorization, including "Read-only" and "Read/edit" modes for documents.

For an international company such as HARTMANN, the privacy of sensitive data (see MAN-M5.5-01 "Data Protection Manual", (BIC: F04)), such as customer, staff and patient data, and the protection of this data in line with legal requirements, is a very important issue. For this reason, a company-wide data protection policy has been adopted that guarantees a consistent level of data privacy throughout the company worldwide.
At the same time, all members of staff can access information on the topic of data privacy, as well as on the protection of confidential health data.

8.4.3. Corrective and preventive action (CAPA)

All criticisms and complaints of customers (see Chapter 9.1.2), deviations in internal as well as external audits, or need for action on the basis of the management review result in the continuous improvement process (see Chapter 8.1.1), in which the definition, implementation and documentation, including control of corrective actions, is appropriately initiated.

Our corrective action program may include:

- Review of non-conformities and trends in customer complaints;
- Root-cause analyses of non-conformities to prevent recurrences;
- Data and trend analyses on the effectiveness of previous actions;
- Communication of actions taken and their effectiveness to the executive committees depending on the risk;
- Process changes on the basis of corrective actions;
- Publication of urgent safety information (FSN Field Safety Notices or advisory notices) and product recalls;
- Elimination of non-conformities of the IMS and
- Review of the effectiveness of corrective actions.

Our preventive action program may include:

- Analyses of processes relevant to product quality in order to prevent non-conformities;
- Defining the implementation;
- Data and trend analyses on the effectiveness of previous actions;
- Process changes on the basis of preventive actions;
- Elimination of potential non-conformities of the IMS;

- Assessments of projects and objectives;
- Communication of actions taken and their effectiveness; and
- Review of the effectiveness of preventive actions.

8.5. Research and technology (M4 – BIC: S10)

HARTMANN Group itself conducts research into new healing concepts and for this purpose pursues in depth dialogue with research institutes. The objective of the company is to constantly improve the products and thus the benefits to customers and patients by drawing on new technologies or even new product categories in the development process – see also Chapter 8.2.4, 9.2 and 9.3.

8.6. Governance (M5 – BIC: F01)

PAUL HARTMANN SPAIN is aware of its responsibility to society and therefore also seeks to make its contribution to safeguarding society and to the independence of service providers in their therapeutic decision-making.
This is manifested not only in the business principles of the company (see also Chapter 2) but also in the commitment of the company within industry associations and standardization committees that define standards for product safety – see also Chapter 8.2.4.

HARTMANN has summarized the key aids to orientation on the topic of compliance in its Code of Conduct.

8.7. Finance management (M6 – BIC: M03)

Our company has the corporate form of a public limited company and is therefore subject to the business principles for incorporated organizations. This is assured by an internal controlling system and accounting process.
PAUL HARTMANN SPAIN strives for long-term commercial success, which therefore necessitates the regular risk assessment of the company and of the future market development. This is achieved with a systematic procedure that draws on the methods of product risk management (see Chapter 10.6).

8.8. Mergers and acquisitions (M7 – BIC: M04)

The options for permanently protecting the company's future include investments and acquisitions of companies. For this purpose, PAUL HARTMANN SPAIN contributes to the systematic monitoring the global sellers' market so that it can make decisions on the basis of the data obtained during the management review.

9. Core processes (C)

9.1. Distribution process (C1 – BIC: C01)

9.1.1. Product and service requirements

The product design and the design of the service processes are guided by the customers' wishes and legislative requirements. In addition, the standard procedure for orders is to check whether the defined properties of the products are consistent with the established specification.
User training sessions are defined within the scope of CP-5.4-01 "*Installation, servicing and repair of reusable medical devices"* (BIC: C03-07).

9.1.2. Communication with customers

Feedback from our customers is essential to maintaining the high-quality level of our products and services to which we aspire. This customer satisfaction is measured on the one hand by complaint management in accordance with CP-S2.5-01 "*Complaints management for products*" (BIC: S02-02) and on the other hand by direct contact between the customers and the medical devices advisers.

9.2. Marketing process (C2 – BIC: C02)

PAUL HARTMANN SPAIN operates with its product portfolio in the so-called legally regulated area. This means that the distribution and marketing of all products are subject to stringent legal regulation. Therefore, all advertising statements are based on the development results (see Chapter 9.3), and they systematically comply with the labelling process.
For planned development projects, the research (see Chapter 8.5) is accompanied by market research, in order to be able to provide qualified development input on user requirements and restrictions (usability).

The entire life cycle of all PAUL HARTMANN SPAIN products is managed with a Corporate process, described in CP-C2.1-01 *"Product Lifecycle Management (PLM)"* (BIC: C02). It manages and controls all relevant activities from the initial product idea to product development and / or supplier processing, product launches, change management and maintenance, right through to phasing out. Underlying processes and documents can differ for non-medical products such as pharmaceuticals, biocides, cosmetics, personal protective equipment, and consumer goods. See also chapter 10.2.

The required material master data are compiled as part of material data management (MDM - Material Data Management) and serves to uniquely identify our products (UDI - Unique Device Identification). It enables the identification of our products and thus also facilitates the traceability of products.

The MDM process according to CP-C2.1-02 "*Material Master Data Management*" (BIC: C02-08-02) not only determines how material master data records and articles are created/changed, but also controls the creation/changes of UDI records and forwarding to the UDI database according to CP-C2.1-04 *"Unique Device Identification UDI"* (BIC: C02-08-02).

9.3. Development process (C3 – BIC: C02)

The product and process development of HARTMANN Group is defined as follows:

The first step in the process is planning the development project, which defines the responsibilities and phases of the project, including the phase requirements, resources, and scheduling. All phases and their inputs and outputs are documented, and each is concluded with a review.

The input documents combine the data of all departments having customer contacts (see Chapters 8.5 and 9.1) and among other considerations they define the performance requirements (user requirement specification) and the intended purpose.

The outputs of the development process are the product specification and the requirements for the production processes, inspections and testing, packaging, labelling and, if appropriate, maintenance of the products. In

each planned phase of the development process, the output of the phase is subjected to a review of appropriately predefined requirements, including risk management (see Chapter 10.6), and thus verified.
The development results in validated products and processes that, along with qualified facilities, ensure the development, production and marketing of products that meet requirements and are safe. The prerequisites for this are careful design planning and mastery of processes, as well as suitable premises, computer systems and methods.
On the basis of risk analyses, validation ensures that the defined requirements are met and permanently fulfilled and that processes are under control and remain so.
After completion of product and process validation and the associated approval for production, the regulatory process of evaluating conformity can begin, and the design can be transferred into production.

The Design History File (DHF) is the collection of all technical documentation generated as part of the Product Design and Development Process (PDP) project. The Device Master Record (DMR) contains all documents needed to produce a specific product. The DMR and the DHF are stored in TeamCenter database.

9.4. Supplier processes (C4 – BIC: S09)

The product development process defines the requirements for the materials to be procured, for the equipment and for the services. The requirements in terms of the qualification of suppliers, including certification requirements and the incoming goods inspection, are also developed here. This includes any incoming goods inspections that may be outsourced to the supplier.

9.5. Production and service processes (C5 – BIC: C03)

The manufacture of the various products is defined in detail in the production process and in site-specific manufacturing instructions. All production-related documentation relevant to product and quality is archived in the Device History Record (DHR). A DHR must be maintained for each batch.

As described under Scope in Chapter 6.1, several production sites are covered by the IMS described here.
They are respectively presented briefly in a site-specific annex (see Annexes 10 and 11) of this manual.

9.5.1. Customer ownership

At PAUL HARTMANN SPAIN, customer ownership may occur in the context of devices to be returned. In the event of a complaint, the proper procedure is set out in CP-S2.5-01 "*Complaints management for products"* (BIC:S02-02) and, for services, in CP-C5.4-01 "*Installation, servicing and repair of reusable medical devices*" (BIC:C03-07).
Customer ownership is clearly labelled, protected from loss and damage, and treated with as much care as if it was the own property. This process also applies equally to the property of external providers.
There is no customer ownership in the production unit PHSA and PHISA.

9.6. Logistics processes (C6 – BIC: C03)

PAUL HARTMANN SPAIN is responsible for preservation of the products in warehousing and distribution. Therefore, the processes of warehousing and distribution are defined in accordance with the development results. A further objective of PAUL HARTMANN SPAIN is also maintaining the constant ability of the company to make deliveries.

10. Supporting processes (S)

10.1. Project management (S1 – BIC: S01)

HARTMANN Group standards in terms of change processes are high, as the prerequisite to the long-term success of the company is the continuous adaptation of the company and its product and service portfolio. Therefore, starting from a defined size or level of significance, all projects must be conducted in accordance with the MAN-S1-01 project management manual.

10.2. Regulatory compliance (S2 – BIC: C03)

The product portfolio of PAUL HARTMANN Spain comprises products from various fields of law and licensed in many sales markets, which are regulated by specific legislation (see also organizational knowledge, chapter 8.2.4).
The Product Lifecycle Management process (see chapter 9.2 or CP-C2.1-01 *"Product Lifecycle Management (PLM)"* (BIC: C02)) forms the parenthesis that controls and complies with all necessary processes and documentation throughout the entire product lifecycle which will lead to compliance of the products in all sales markets.
The Technical Documentation enables the manufacturer and the relevant Authorities to assess the product conformity to the requirements of the applicable legislation (for medical devices, the MDD or MDR). The Technical documentation is stored in the TeamCenter database.
The intended use of a new product is already required in the idea phase. Building on this, together with the intended geographical scope, the regulatory requirements are determined in the design phase (see CP-S2.1-01 *"Regulatory Process for Placing Products on the Market"* (BIC: C02-04-02), "Annex 4: Regulatory Strategy").
In the subsequent development phase, which includes the product design and development process (see Chapter 9.3 or CP-C3.1-01 *"Product design and development process"* (BIC: C02-03-01)), the documents required for the respective conformity assessment procedure are considered from the outset (see CP-S2.2-01 *"Regulatory product documentation"* (BIC: C02-04-01)).

For medical devices, the essential requirements (MDD, Annex I) and the Basic Safety and Performance Requirements (MDR, Annex I; see also CP-S2.2-01 "*Regulatory Product Documentation*" (BIC: C02-04-01), "Annex 20: Essential Requirements for Medical Devices" and "Annex 6: General safety and performance (GSPR) Checklist") form the basis from which all further applicable processes are derived. In addition, the applicable norms and standards are determined. The PLM process assumes this control function.
Risk management (see Chapter 10.6), in which the safety of the products is comprehensively examined, and existing risks are reduced as far as possible, should be emphasized. This is based on the generally recognized state of the technology.
Another central document is the clinical evaluation of products (see Process CP-C3.3-01 *"Clinical Evaluation of Medical Devices"* (BIC: C02-04-03)). The effectiveness of the products, measured against the legally required state of the science and the current state of the technology, is investigated here. The residual risk from the risk management is compared and it is checked whether the medical benefit outweighs the residual risk.

In the case of products for which any entity of the HARTMANN Group is not itself legal manufacturer, the proof of conformity of the purchased products is checked in the PLM. If these originate from other regulatory areas, the determination of the requirements to be fulfilled is determined in the conception phase of the PLM.

The MDM process, also triggered by the PLM, ensures that consistent and valid product master data is fed into the central systems (SAP) at any time. From this, the non-variable part of the UDI required under MDR will be created in the future (see chapter 9.2).

In the market phase of the products, feedback on the product is collected in the following processes: Complaint Management (CP-S2.5-01 - BIC: S02-02), Incident Management (CP S2.6-01 - BIC: S02-03), FSCA Management (Recall Plan) (CP-S2.7-01 - BIC: S02-03), Post-Market Surveillance (PMS) (CP-S2.8-01 - BIC: S02-03) and Clinical Evaluation of Medical Devices (CP-C3.3-01 - BIC: C02-04-03). This information serves as input for the regular updating of risk management and clinical evaluations. This may result in design changes to the products, which are initiated via the CAPA (CP-M3.3-01 - BIC: M02-05) or change control process (CP-M3.4-01 - BIC: C02-01-08) and end again in PLM (CP-C2.1-01 - BIC: C02).

With the exception of clinical evaluation, these processes can be used for products from other regulatory areas. Where necessary, special documents to be used for this purpose are stored.

Based on all the Business and Corporate Processes mentioned and other specific Local Procedures and Working Instructions to cover local requirements, it is ensured that the products in the PAUL HARTMANN SPAIN portfolio always comply with the applicable regulations.

10.3. Infrastructure (S3 – BIC: S03)

The necessary equipment of the production facilities and their processes is decided within the development process. This is provided and maintained in accordance with the maintenance plan.
The inspection, testing and measuring devices of PAUL HARTMANN SPAIN are systematically recorded and deployed in accordance with the development results. Based on processability considerations and the requirements of the manufacturers of the inspection, testing and measuring devices, these are regularly subjected to maintenance or calibration in accordance with SOP-S3.2-01a PHE/PHISA "*Management of testing equipment*" (BIC: S07-04).
In addition to the infrastructure described, product hygiene must also be controlled in the context of product safety for many PAUL HARTMANN SPAIN products. Hygiene management systems have been introduced for this purpose.
The hygiene concept for the cleanroom at the Production unit PHSA is described in Annex 12 "*Hygiene concept Medical production Mataró (PHSA)*".
The hygiene rules and regulations are described in Local SOP / WI within the scope of this management manual in MAN-M1.3-03 "*Management manual: Controlled production conditions*".

10.4. Health, Safety and Environment (HSE) (S4 – BIC: S04)

Besides product safety, however, the occupational safety of our colleagues is an essential factor in employee satisfaction and thus is a prerequisite for long-term performance and quality of work, as well as the reduction of sick leave.
The HSE department combines expertise in processes pertaining to occupational safety, fire safety, environmental protection, site security, occupational medicine, and active health management. There are high standards for ensuring low numbers of sick days, high employee satisfaction, for protecting the environment and our sustainable use of resources, as well as for preventing emergencies.

10.5. IT management (S5 – BIC: S05)

The basic concept behind our IT standards is compliance with regulatory requirements and the implementation of IT best practices. HARTMANN Group has therefore created a process chain that safeguards its IT systems and, for example, also includes the validation of the application of computer software.

10.6. Risk management (S6 – BIC: C02)

During the development process, the risks of product use and also of product manufacture are analyzed in accordance with EN ISO 14971, assessed and measures are implemented to reduce the residual risk.

On the basis of the rules of EN ISO 14971, a regular risk assessment with respect to the product portfolio see above) and of the future market development is also conducted for the entire company in order to assure the long-term success of PAUL HARTMANN SPAIN.

This includes designing key company processes on a risk-based approach (see also Chapter 7.2), whereby the company also uses risk management methods.

10.7. Measurements and analyses (S7 – BIC: S07)

PAUL HARTMANN SPAIN continually conducts a technological market monitoring process with regard to the usability and compatibility of its products. This also includes monitoring the regulations and standards applicable to the products in the markets that it serves (see Chapter 10.2).

10.7.1. Monitoring and measurement of products and processes

Appropriate methods for inspection and testing of products as well as manufacturing, warehousing, transport and service processes are developed during the development process. The sense and purpose of the inspections and tests is to demonstrate compliance with the defined specifications. The inspections and tests are performed at PAUL HARTMANN SPAIN in accordance with planned processes.

10.7.2. Data analysis

PAUL HARTMANN SPAIN has established a reporting structure, which also generates data, including for the management review. On the basis of this data, the effectiveness of the IMS is analyzed and the need for change or improvement is estimated.
The use of statistical methods with reasons for sample sizes or data evaluation methods is decided on a case by- case basis and is integrated into the respective process descriptions.

10.8. Operation Finance Processes (S8 – BIC: S08)

Our financial department takes care of safeguarding Accounting, Treasury and Tax compliance and governance. In addition, Finance and Controlling departments also specify and optimize the operating processes in the areas of Finance, Controlling and Insurance, and secure the financial resources of the HARTMANN GROUP.

11. Annexes

Document number	Document Title
Annex 0	Change Protocol
Annex 1	Regulatory Scope
Annex 2	Withdrawn
Annex 3	Integrated Policy
Annex 4	Withdrawn
Annex 5	Process Map (Annex recovered)
Annex 6	6A: Process List PHE
	6B: Process List PHISA
Annex 7	Withdrawn
Annex 8	8A: Interested parties PHSA and PHISA
	8B: Interested parties LHSA
Annex 9	Withdrawn
Annex 10	Presentation of Production site Mataró (PHSA&LHSA)
Annex 11	Presentation of Production site Montornés (PHISA)
Annex 12	Hygiene concept Production Medical site Medical Mataró (PHSA)
Annex 13	Interaction matrix PHE