

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C899700

Initial certification date:
2018-12-17

Expiry Date:
2029-09-29

This is to certify that the management system of

Coloplast A/S

Holtedam 1, Humlebaek, Denmark, 3050

F005629

and the sites as mentioned in the appendix accompanying this certificate
has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 820

This certificate is valid for the following scope:

The registration covers the Quality Management System for the design and manufacture of penile prosthesis, testicular prosthesis, implantable meshes, surgical instruments, stents, intravesical needles, irrigation and drainage devices, catheters, sutures, suturing system, anal plugs, external catheters, urine bags and accessories for the area of gynecology, urology, and continence care. Design and manufacture of ostomy appliances, irrigation systems, and accessories for the area of ostomy care.

Design and manufacture of wound dressings, skin care products, and accessories for the area of wound and skin care.

Design, development, and manufacture of voice restoration systems including instruments for insertion, pulmonary rehabilitation systems including attachments, covers and accessories, jaw motion, and swallowing rehabilitation systems, and electrolarynx

Place
Høvik

Effective Date:
2026-09-30



DNV Product Assurance AS is an MDSAP
Recognized Auditing Organization

For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway



Hazem Tinawi
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.

Appendix to Certificate

Locations included in the certification are as follows:

Site Name (Facility ID)	Site Address	Site Scope
Coloplast A/S (HQ) (REP F005629)	Holtedam 1 & 3, Humlebaek, 3050 Denmark	Design, Management and Quality Assurance of Ostomy Care, Wound Care, Continence Care, Skin Care Urology, Intermediate and Consumer Products and Design of Ostomy Care, Wound Care, and Continence Care. Information Technology
Coloplast A/S (REP F005655)	Aa. Louis-Hansens Alle 15, Moerdrup, 3060 Espergarde Denmark	Dependent processes covered at this location: Management, Quality assurance and Manufacture of Intermediates, Continence Care Devices and Wound Dressings
Coloplast Hungary KFT (REP F005704)	Kerek utca 3, 2800 Tatabanya Hungary	Dependent processes covered at this location: Manufacturing and Packaging of products for Ostomy Care and continence care, Packaging of finished products and distribution
Coloplast Hungary KFT (REP F005668)	Büzavirág út 15, 2800 Tatabánya, Hungary	Dependent processes covered at this location: Management, Quality assurance, Manufacturing and Packaging of products for Ostomy Care, Continence Care, and Urology Care
Coloplast Hungary KFT (REP F005668)	Kerek utca 4, 2800 Tatabanya, Hungary	Management, Quality assurance and Manufacture of Ostomy
Coloplast Hungary KFT (REP F005703)	Coloplast utca 2, 4300 Nyírbátor, Hungary	Dependent processes covered at this location: Management, Quality Assurance and Manufacture of Ostomy Care, Wound Dressings and Continence Care Devices
Coloplast Manufacturing France SAS (REP F005695)	20 Rue Blaise Pascal, 24200, Sarlat- La-Canéda, France	Storage and Shipping Processes
Coloplast Manufacturing France SAS (REP F005695)	9 Avenue Edmond Rostand, 24602, Sarlat-La-Canéda, France	Dependent processes covered at this location: Management, Quality Assurance, Purchasing, Design and Manufacture of stents, irrigation and drainage devices, catheters, testicular prosthesis, intravesical needles and surgical instruments
Coloplast Manufacturing France SAS (REP F005679)	Lieudit La Boursidiere Centre d'Affaires, 92350 Le Plessis Robinson, France	Dependent processes covered at this location: Management (Regulatory affairs), for stents, irrigation and drainage devices, catheters, testicular prosthesis, intravesical needles and surgical instruments
Coloplast Manufacturing France SAS (REP F005679)	2 Rue Jacqueline Auriol, 91220 Le Plessis-Pate, France	Warehousing, Repackager, Relabeler, Foreign exporter, and distribution of stents, irrigation and drainage devices, catheters, testicular prosthesis, intravesical needles and surgical instruments
Coloplast Manufacturing US, LLC (REP F005699)	680 E Travelers Trl Ste 800, Burnsville, Minnesota, US	Storage and shipping

Site Name (Facility ID)	Site Address	Site Scope
Coloplast Manufacturing US, LLC and Coloplast Corporation (REP F005699)	1601 West River Road North, Minneapolis, MN 55411 USA	Dependent processes covered at this location: Management, Quality Assurance, Purchasing, Design and Manufacturing of Surgical Instruments, Sutures, Suturing System and Surgical Implants, for the area of Urology and incontinence care
Coloplast Manufacturing US, LLC (REP F007447)	4008 Heritage Drive, Brookshire, TX 77423 USA	Dependent processes covered at this location: Management and Distribution Processes
Coloplast Volume Manufacturing Costa Rica SA (REP F005680)	Calle 58, Zona Franca La Lima, La Lima, Guadalupe, 30106 Cartago Costa Rica	Management, Quality assurance and Manufacture of Ostomy care products and Continence care products
Coloplast (China) Ltd. (REP F005700)	No. 202, Baocheng Road, Xiangzhou District Zhuhai, 519030 China	Dependent processes covered at this location: Management, Quality assurance and manufacture of ostomy care, and continence care devices.
Atos Medical AB (REP F006983)	Kraftgatan 8, 242 35 Hörby, Sweden	Design, development, manufacture, and distribution of voice restoration systems including instruments for insertion, pulmonary rehabilitation systems including attachments, covers and accessories, jaw motion and swallowing rehabilitation systems, electrolarynx.
Atos Medical AB (REP F006983)	Medicingatan 3; SE-242 34 Hörby; Sweden	Warehousing