

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
10000459108-PA-NA-DNK

Initial certification date:  
23 September 2008

Valid:  
30 September 2026 – 29 September 2029

This is to certify that the management system of

**Coloplast A/S**

Holtedam 1, 3050 Humlebæk, Denmark

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 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**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 and date:  
Høvik, 01 October 2026



For the issuing office:  
**DNV Product Assurance AS**  
Veritasveien 1, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

## Appendix to Certificate

### Coloplast A/S

Locations included in the certification are as follows:

| Site Name                          | Site Address                                                                 | Site Scope                                                                                                                                                                                                                      |
|------------------------------------|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Coloplast A/S                      | Holtedam 1 & 3, 3050 Humlebæk, 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                      | Aa. Louis-Hansens Allé 15, Mørdrup, 3060 Espergærde, Denmark                 | Management, Quality assurance and Manufacture of Intermediates, Continence Care Devices and Wound Dressings.                                                                                                                    |
| Coloplast Manufacturing France SAS | 9 Avenue Edmond Rostand, CS 70218, 24206, Sarlat-la-Canéda, Cedex, France    | 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 | Lieudit La Boursidière Centre d'Affaires, 92350, Le Plessis Robinson, France | Management (Regulatory affairs), for stents, irrigation and drainage devices, catheters, testicular prosthesis, intravesical needles and surgical instruments.                                                                  |
| Coloplast Manufacturing France SAS | 20, rue Blaise Pascal, 24200, Sarlat-la-Canéda, France                       | Storage and Shipping Processes                                                                                                                                                                                                  |
| Coloplast Manufacturing France SAS | 2, Rue Jacqueline Auriol, 91220, Le Plessis Pâté, France                     | Warehousing, Repackager, Relabeler, Foreign exporter, and distribution of stents, irrigation and drainage devices, catheters, testicular prosthesis, intravesical needles and surgical instruments.                             |
| Laboratoires Coloplast SAS         | 35 bvd de Courcerin, 77185, Lognes, France                                   | Warehouse and Distribution                                                                                                                                                                                                      |
| Coloplast Hungary KFT              | Búzavirág út 15, 2800 Tatabánya, Hungary                                     | Management, Quality assurance, Manufacturing and Packaging of products for Ostomy Care, Continence Care, and Urology Care.                                                                                                      |
| Coloplast Hungary KFT              | Coloplast utca 2, 4300 Nyírbátor, Hungary                                    | Management, Quality Assurance and Manufacture of Ostomy Care, Wound Dressings and Continence Care Devices.                                                                                                                      |
| Coloplast Hungary KFT              | Kerek utca 3, 2800 Tatabánya, Hungary                                        | Manufacturing and Packaging of products for Ostomy Care and continence care, Packaging of finished products and distribution.                                                                                                   |
| Coloplast Hungary KFT              | Kerek utca 4, 2800 Tatabánya, Hungary                                        | Management, Quality assurance and Manufacture of Ostomy.                                                                                                                                                                        |
| Coloplast Corporation              | 1601 West River Road North, Minneapolis, MN, 55411, USA                      | Management, Quality Assurance, Purchasing, Design and Manufacturing of Surgical Instruments, Sutures, Suturing System and Surgical Implants, for the area of Urology and incontinence care.                                     |

| Site Name                                  | Site Address                                                                                   | Site Scope                                                                                                                                                                                                                                                                                  |
|--------------------------------------------|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Coloplast Manufacturing US, LLC            | 1601 West River Road North, Minneapolis, MN, 55411, USA                                        | 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 Burnsville | 680 E Travelers Trl Ste 800, Burnsville, Minnesota, 55337, USA                                 | Warehouse                                                                                                                                                                                                                                                                                   |
| Coloplast Manufacturing US, LLC            | Kingsland Ranch Logistics Park, Building 2, 4008 Heritage Drive, Brookshire, Texas, 77423, USA | Management and Distribution Processes                                                                                                                                                                                                                                                       |
| Coloplast (China) Ltd.                     | No. 202, Baocheng Road, Xiangzhou District, Zhuhai, 519030 China                               | Management, Quality assurance and manufacture of ostomy care, and continence care devices.                                                                                                                                                                                                  |
| Coloplast Volume Mfg. Costa Rica SA        | 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 Productos Medicos, S.A.          | Arroyo de los Prados, 5, Polígono Industrial las Arenas, 28320, Pinto, Madrid, Spain           | Warehouse and Distribution                                                                                                                                                                                                                                                                  |
| Coloplast S.p.A                            | Via del Commercio Associato 15, 40127 Bologna, Italy                                           | Management, warehousing and distribution processes                                                                                                                                                                                                                                          |
| Coloplast Ltd                              | Unit 2, Artemis Way Alwalton Hill, Peterborough, PE7 3FU, United Kingdom                       | Management, warehousing and distribution processes                                                                                                                                                                                                                                          |
| Coloplast Distribution GmbH                | Werner-Schröder-Strasse 1, 21035 Hamburg, Germany                                              | Management, warehouse and Distribution                                                                                                                                                                                                                                                      |
| Coloplast AB                               | Energigatan 21, 434 37 Kungsbacka, Sweden                                                      | Management, warehousing and distribution processes                                                                                                                                                                                                                                          |
| Coloplast Czech s.r.o.                     | Průmyslová 1504, 69123 Pohořelice, Czech Republic                                              | Warehouse and Distribution                                                                                                                                                                                                                                                                  |
| Atos Medical AB                            | Kraftgatan 8, SE-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 and tympanostomy tubes. |
| Atos Medical AB                            | Medicingatan 3; SE-242 34 Hörby; Sweden                                                        | Warehousing                                                                                                                                                                                                                                                                                 |