# EU Quality Management System Certificate

Certificate no.:
10000376655-PA-NoMA-DNK

Initial certification date:
26 August 2021

Valid Until:
12 August 2031

This is to certify that the quality system of

## Coloplast A/S

Holtedam 1, 3050 Humlebaek, Denmark
SRN: DK-MF-000025526

For design, production, and final product inspection/testing of:

**Foam wound dressings, Foam wound dressings with silver, Foam wound dressings with Ibuprofen, Antimicrobial Moisture Wicking Fabric with Silver, Superabsorbent wound dressings, Catheters for intermittent catheterization, Surgical accessories, Urological stents, Penile implants, Penile implant accessories, Drainage bags, Endourological instruments, Surgical Mesh, Single Incision Sling System, Urine bags, Penile prosthesis, Hydrocolloid wound dressings and Wound debridement pad, Gelling fiber dressings, Urethral dilation, Urological devices, urological accessories, Urinary/Suprapubic Indwelling Catheters and ostomy devices, Surgical Drainage, Hydrogel wound dressings**

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:
**Høvik, 13 August 2026**

For the issuing office:
**DNV Product Assurance AS – Notified Body 2460**
**Veritasveien 1, 1363 Høvik, Norway**

Khanpara B.C.

**Bhautik Khanpara**
Management Representative

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

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

**Jurisdiction**

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Report No. | Issue Date |
|---|---|---|---|
| 0.0 | Original Certificate | 5254234 | 26 August 2021 |
| 1.0 | Addition of Speedicath control | 2499147 | 17 December 2021 |
| 2.0 | Addition of Furlow | 2499161 | 27 December 2021 |
| 3.0 | Addition of Biosoft duo | 2522909 | 03 February 2022 |
| 4.0 | Blockchain data Changes | NA | 03 February 2022 |
| 5.0 | Addition of Titan and Titan Accessories | 2522908 | 06 April 2022 |
| 6.0 | Revision of wording and product name on certificate | 2703041 | 06 May 2022 |
| 7.0 | Addition of drainage bags | 2707869 | 16 May 2022 |
| 8.0 | Editorial change | NA | 30 May 2022 |
| 9.0 | Addition of Steerable Pusher and Hybrid Guidewire | 2499146 | 17 June 2022 |
| 10.0 | Addition of Biatain Ag Adhesive Biatain Ag Non-Adhesive and Biatain Silicone Ag | 2522905 | 30 June 2022 |
| 11.0 | Editing Furlow to be defined as reusable surgical instruments. Include Rossello and Brooks Dilator to reusable surgical instrument product list. | 2706360 | 13 July 2022 |
| 12.0 | Addition of Restorelle® Polypropylene Mesh and Altis® Single Incision Sling System | 2499115 | 19 October 2022 |
| 13.0 | Addition of Urine bags | 2701701 | 25 October 2022 |
| 14.0 | Addition of Genesis and adding sites relevant for production of devices included in this certificate. Adding EU technical documentation assessment certificate reference for Biosoft duo | 2499117 | 22 November 2022 |
| 15.0 | Move of location Coloplast Manufacturing France SAS from Champlan to Le Plessis-Pâté Revise EU technical documentation certificate number to Genesis | 2793908 | 06 December 2022 |
| 16.0 | To add Soft polyurethane (PU-S) double loop ureteral stents, Silicone double loop ureteral stents, Comfeel Plus, Vortek and Vortek hydro-coated double loop ureteral stents with hydrogel coating, Vortek Tumor stent - double loop ureteral stents, Biosoft duo multi-length hydro-coated double loop ureteral stents, Silicone hydro-coated double loop ureteral stents, Silicone Pyelostent double loop ureteral | 2499125 | 03 February 2023 |

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| | stents, Silicone Stenostent double loop ureteral stents, Rigid polyurethane (PU-R) double loop ureteral stents, Alprep Pad. Editorial change of name for Biosoft® duo double loop ureteral stents | | |
| 17 | Include Wound debridement pad in scope to cover Alprep pad, to add Connectors, Catheter valve and Urethral dilation devices. | 2797428 | 21 February 2023 |
| 18 | Include Endourological instrument- Non steerable pusher | 2807829 | 02 May 2023 |
| 19 | Include Band-Aid hydrocolloid gel plaster | 2727928 | 16 June 2023 |
| 20 | Include Single loop ureteral stent, Elefant Suction-Irrigation Devices, Retrace ureteral access sheath, Ureteral dilators, Comfeel Plus Contour, Comfeel Plus Transparent, Guidewires – Stainless Steel | 2738064 | 20 July 2023 |
| 21 | Include Aris introducers and Dormia PCNL.<br>Place urological accessories under same group.<br>Move Biosoft® duo double loop ureteral stents to the Urological stents. | 2712975 | 27 September 2023 |
| 22 | Include Dormia No-Tip, Dormia N.Stone and Percutaneous Nephrostomy Dilators | 2997369 | 07 November 2023 |
| 23 | Include Biatain Fiber and Freudenberg Introducer | 2499173 | 01 December 2023 |
| 24 | Include Ureterostomy catheter and Short term enterocystoplasty catheter | 2679416 | 07 December 2023 |
| 25 | Include Biatain Silicone Sacral and Multishape. Move Biatain Fiber to other wound dressings and add intended purpose. Add Costa Rica site. | 2499172 | 21 December 2023 |
| 26 | Include Short term uretero-sigmoidostomy catheter, Single loop ureterostomy catheter, Percutaneous puncture needles, and ureteric catheters | 3051268 | 19 January 2024 |
| 27 | Include Folysil Catheters and SenSura Mio Baby | 2499151 | 5 February 2024 |
| 28 | Include Biatain Silicone Fit | 3051268 | 04 March 2024 |
| 29 | Include X-Flow prostatectomy catheter, Hydro X-Flow prostatectomy catheter, PA/PU double loop ureteral stent sets,Detour and Bonee | 2499142 | 16 April 2024 |
| 30 | Include Neoplex catheters without balloon. Corrected address for site 2 Espergærde. | 2499113 | 27 May 2024 |
| 31 | Include Floppy tip hydro-coated ureteric catheter | 3123417 | 19 June 2024 |
| 32 | Include Virtue Male Sling System | 2499113 | 10 July 2024 |

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| 33 | Include Biatain Superabsorber dressing | 2930666 | 28 August 2024 |
| 34 | Include Biatain Ibu Non-Adhesive and Biatain Ibu Soft-Hold dressings | 2499129, 2499130 | 25 November 2024 |
| 35 | Include Assura/Alterna Post Op Ostomy bag | 3071290 | 20 January 2025 |
| 36 | Admin correction: change product name Assura/Alterna Post Op Ostomy bag to Sterile ostomy bags | 3071290 | 22 January 2025 |
| 37 | Admin correction: change of product description from Ostomy baseplates and bags (refeeding) to Ostomy bags | 3071290 | 23 January 2025 |
| 38 | Include Supraflow supra-pubic drainage set with silicone balloon catheter and Cystodrain integral set for supra-pubic drainage | 2499143 | 07 February 2025 |
| 39 | Include Silicone nephrostomy balloon catheter | 2499157 | 02 May 2025 |
| 40 | Include InterDry | 2499116 | 21 May 2025 |
| 41 | Include Percutaneous nephrostomy set with simple loop vortek catheter | 2954648 | 04 June 2025 |
| 42 | Include Vortek J and malecot nephrostomy catheters | 3339904 | 10 June 2025 |
| 43 | Include Escat transcystic drains in PVC, Multitubular drain silicone, Tubular drains silicone, Delbet drains, Multi-perforated tubular drain silicone radiopaque | 2979526 | 13 November 2025 |
| 44 | Include Purilon Gel | 2499154 | 26 February 2026 |
| 45 | Removal of Biatain Ag Adhesive foam dressing device, following discontinuation | 3457456 | 12 March 2026 |
| 46 | Addition of Biatain Adhesive | 2499174 | 02 July 2026 |
| 47 | Addition of Biatain Non Adhesive | 2499174 | 21 July 2026 |
| **48** | **Renewal** | **3583222** | **13 August 2026** |

Products covered by this Certificate:

| **Product Description (and intended purpose for class IIb)** | **Product Name** | **Class** |
|---|---|---|
| Silicone dressings<br>Moist wound healing and exudate management | Biatain Silicone | IIb |
| | Biatain Silicone Lite | IIb |
| | Biatain Silicone Non-Border | IIb |
| Silicone dressings<br>Moist wound healing and exudate management and may also be used as part of pressure injury prevention therapy | Biatain Silicone Sacral and Multishape | IIb |
| | Biatain Silicone Fit | |

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| Gelling fiber dressing<br>Moist wound healing and exudate management of moderate to high exuding wounds, including cavity wounds | Biatain Fiber | IIb |
| Superabsorbent wound dressing<br>The product is intended for moist wound healing and exudate management | Biatain Superabsorber | IIb |
| Urinary Catheters | Sterile intermittent catheters | Is |
| Surgical instruments | Reusable surgical instruments | Ir |
| Penile implants<br>System surgically implanted for the management of erectile dysfunction | Titan | IIb* |
| Penile implant accessories<br>To facilitate assembly and implant of the Titan IPP | Titan | IIb* |
| Drainage bags | Sterile drainage bags | Is |
| Endourological instrument | Steerable Pusher | IIa |
| | Non steerable pusher | IIa |
| | Hybrid Guidewire | IIa |
| | Guidewires – Stainless Steel | |
| Foam dressing with silver | Biatain Ag Non-Adhesive | III* |
| Foam dressing with ibuprofen | Biatain Ibu Non-Adhesive | III* |
| Foam dressing with ibuprofen | Biatain Ibu Soft-Hold | III* |
| Silicone foam dressing with silver | Biatain Silicone Ag | III* |
| Surgical Meshes | Restorelle® Polypropylene Mesh | III* |
| | Virtue Male Sling System | III* |
| Single Incision Sling System | Altis® Single Incision Sling System | III* |
| Antimicrobial Moisture Wicking Fabric with Silver | InterDry | III* |
| Urine bags | Sterile urine collection bags | Is |
| Penile prosthesis | Genesis® Malleable Penile Prosthesis | IIb* |
| Urological stents<br>Drainage of the upper urinary tract over fistulas or ureteral obstacles and healing of the ureter | Soft polyurethane (PU-S) double loop ureteral stents | IIb* |
| | Silicone double loop ureteral stents | IIb* |
| | Vortek® double loop ureteral stents | IIb* |
| | Vortek® hydro-coated double loop ureteral stents | IIb* |

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| | Vortek® Tumor stent - double loop ureteral stents | IIb* |
| | Biosoft duo multi-length hydro-coated double loop ureteral stents | IIb* |
| | Rigid polyurethane (PU-R) double loop ureteral stents | IIb* |
| | Silicone hydro-coated double loop ureteral stents | IIb* |
| | Biosoft® duo double loop ureteral stents | IIb* |
| | Double loop ureteral stent set in polyamide | IIb* |
| | Double loop ureteral stent set in polyurethane | IIb* |
| Urological stents<br>Drainage of the upper urinary tract and ureter healing during management of localized stenosis of ureteropelvic junction. | Silicone Pyelostent double loop ureteral stents | IIb* |
| Urological stents<br>Drainage of the upper urinary tract and ureter healing during management of ureteral stenosis. | Silicone Stenostent double loop ureteral stents | IIb* |
| Urological Implants<br>Long-term palliative treatment of ureteral obstruction. | Detour subcutaneous ureteral bypass | IIb* |
| Hydrocolloid wound dressings | Band-Aid hydrocolloid gel plaster for minor wounds<br>Band-Aid hydrocolloid gel plaster for blisters | IIa |
| Hydrocolloid wound dressing Moist wound healing and exudate management | Comfeel Plus | IIb |
| | Comfeel Plus Contour | IIb |
| | Comfeel Plus Transparent | IIb |
| Wound debridement pad | Alprep Pad | Is |
| Urological accessories | Sterile Connectors | Is |
| | Sterile Tuohy Borst Adapter | Is |
| | Sterile Catheter valve | Is |
| | Sterile Urethral dilations | Is |
| | Sterile Ureteral dilators | Is |
| | Freudenberg Introducer | Is |

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| | Sterile Percutaneous nephrostomy dilators | IIa |
| | Ureteric catheter for retrograde uretero-pyelography | Is |
| | Bonee needle for bladder injection | IIa |
| Urological devices | Percutaneous puncture needles | IIa |
| Urinary/Percutaneous Indwelling Catheters | Single loop ureteral stent | IIb |
| | Ureterostomy catheter | IIb |
| | Folysil Silicone Catheter | IIb |
| | Folysil Silicone Catheter - Long-term | IIb* |
| | Short term enterocystoplasty catheter | IIa |
| | Short term uretero-sigmoidostomy catheter | IIa |
| | Single loop ureterostomy catheter | IIb |
| | Ureteric drainage catheter in neoplex | IIa |
| | Ureteric drainage catheter in polyamide | IIa |
| | Ureteric interventional catheter | IIa |
| | X-Flow prostatectomy catheter | IIa |
| | Hydro X-Flow prostatectomy catheter | IIa |
| | Neoplex catheters without balloon | IIa |
| | Floppy tip hydro-coated ureteric catheter | IIa |
| | Silicone nephrostomy balloon catheter | IIb |
| | Percutaneous nephrostomy set with simple loop vortek catheter | IIb |
| | Vortek J percutaneous nephrostomy catheter | IIb |
| | Vortek malecot percutaneous nephrostomy catheter | IIb |
| Urinary/Suprapubic Indwelling Catheters<br>The devices are intended to be used for:<br>Supra-pubic drainage of urine from the bladder and bladder instillation of physiological saline solution by the supra-pubic rout | Supraflow supra-pubic drainage set with silicone balloon catheter | IIb |
| Urinary/Suprapubic Indwelling Catheters<br>The devices are intended to be used for:<br>- Supra-pubic drainage of the urinary bladder.<br>- Bladder instillation of physiological saline solution by the supra-pubic route.<br>- Replacement of supra-pubic drainage catheter. | Cystodrain integral set for supra-pubic drainage | IIb |

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| Surgical Accessories | Elefant Suction-Irrigation Devices | IIa |
| Ureteral access sheath, Ureteral access sheath with ureteral dilator | Retrace ureteral access sheath | IIa |
| Introducer needles | Aris introducers | IIa |
| Ostomy baseplates and bags (refeeding) | SenSura Mio Baby | IIa |
| Ostomy bags | Sterile ostomy bags | Is |
| Stone extractors | Dormia PCNL | IIa |
| | Dormia No-Tip / Dormia N.Stone | IIa |
| Surgical Drainage | Escat transcystic drains in PVC | IIa |
| | Multitubular drain silicone | |
| | Tubular drains silicone | |
| | Delbet drains | |
| | Multi-perforated tubular drain silicone radiopaque | |
| The device is a hydrogel wound dressing and intended for autolytic debridement, moist wound healing and exudate management of necrotic and sloughy wounds | Purilon Gel | IIb |
| Foam dressings<br>The device is intended for moist wound healing and exudate management. | Biatain Adhesive | IIb |
| | Biatain Non-Adhesive | |

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: C536740, C545160, C566662 NoMa DNK, C569918-NoMa-DNK, C581486 NoMA DNK, C582792 NoMa DNK, C591315 NoMa DNK, C582794 NoMa DNK, C591820 NoMa DNK, C592004 NoMa DNK, C594157 NoMa DNK, C687110, C672963 NoMa DNK, C683022, C677114 NoMA DNK, C677116

The complete list of devices is filed with the Notified Body

## Sites covered by this certificate

| Site Name | Address |
|---|---|
| Coloplast A/S | Holtedam 1, 3050 Humlebaek, Denmark |
| Coloplast A/S | Aa. Louis-Hansens Allé 15, 3060 Espergærde, Denmark |
| Coloplast Hungary KFT | Búzavirág ùt 15, 2800 Tatabánya, Hungary |
| Coloplast Hungary KFT | Coloplast utca 2, 4300 Nyirbátor, Hungary |
| Coloplast Hungary KFT | Kerék utca 3, 2800 Tatabánya, Hungary |
| Coloplast (China) Ltd. | No. 202, Baocheng Rd, Xiangzhou District, Zhuhai 519030, China |
| Coloplast Corporation | 1601 West River Road North, Minneapolis, MN 55411, USA |
| Coloplast Manufacturing US, LLC | 1601 West River Road North, Minneapolis, MN 55411, USA |
| Coloplast Manufacturing France SAS | 9 Avenue Edmond Rostand, CS 70218, 24206 Sarlat-la-Canéda Cedex, France |
| Coloplast Manufacturing France SAS | 20 rue Blaise Pascal, 24200 Sarlat La Canéda, France |
| Coloplast Manufacturing France SAS | 2 Rue Jacqueline Auriol, 91220 Le Plessis-Pâté, France |
| Coloplast Manufacturing France SAS | Lieudit La Boursidière, Centre d'Affaires, 92350 Le Plessis Robinson, France |
| Coloplast Volume Manufacturing Costa Rica SA | Calle 58, Zona Franca La Lima, La Lima, 30106, Cartago, Costa Rica |

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

## Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.