EU Quality Management System Certificate

Certificate no.:
10000376655-PA-NoMA-DNK

Initial certification date:
26 August 2021

Valid Until:
26 August 2026

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, 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, Urethral dilation, Urological device and urological accessories.

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, 27 September 2023

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

Mariann Jeremiassen
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” 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 stents, Silicone Stenostent double loop ureteral stents, Rigid polyurethane (PU-R) double loop ureteral stents, Alprep Pad. Editorial change of	2499125	03 February 2023

	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.** **Place urological accessories under same group.** **Move Biosoft® duo double loop ureteral stents to the Urological stents.**	**2712975**	**27 September 2023**

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	**Product Name**	**Class**
Silicone dressings Moist wound healing and exudate management	Biatain Silicone	IIb
Silicone dressings Moist wound healing and exudate management	Biatain Silicone Lite	IIb
Silicone dressings Moist wound healing and exudate management	Biatain Silicone Non-Border	IIb
Urinary Catheters	Sterile intermittent catheters	Is
Surgical instruments	Reusable surgical instruments	Ir
Penile implants System surgically implanted for the management of erectile dysfunction	Titan	IIb*
Penile implant accessories 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 Adhesive	III*
Foam dressing with silver	Biatain Ag Non-Adhesive	III*
Silicone foam dressing with silver	Biatain Silicone Ag	III*
Surgical Mesh	Restorelle® Polypropylene Mesh	III*
Single Incision Sling System	Altis® Single Incision Sling System	III*
Urine bags	Sterile urine collection bags	Is
Penile prosthesis	Genesis® Malleable Penile Prosthesis	IIb*
Urological stents 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*
	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*
Urological stents 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 Drainage of the upper urinary tract and ureter healing during management of ureteral stenosis.	Silicone Stenostent double loop ureteral stents	IIb*
Hydrocolloid wound dressings	Band-Aid hydrocolloid gel plaster for minor wounds 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**
Urinary/Percutaneous Indwelling Catheters	Single loop ureteral stent	IIb
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**
Stone extractors	**Dormia PCNL**	**IIa**

* 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 and C582792 NoMa DNK, C591315 NoMa DNK, C582794 NoMa DNK, C591820 NoMa DNK, C592004 NoMa DNK

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	Louis-Hansens Allé 15, 3060 Espergærde, Denmark
Coloplast Hungary KFT	Búzavirág út 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

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 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.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.