

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:

10000410282-PA-NA-DNK Rev 1.0

Project No.:

PRJN-199515-2020-PA-DNK

Valid Until

21 September 2023

This is to certify that the quality system of:

Coloplast A/S

Holteådam 1, 3050 Humlebaek, Denmark

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

SURGICAL MESHES, GUIDEWIRES, OSTOMY, WOUND AND SKIN CARE, DRAINAGE, SURGERY, UROLOGY, ANTIMICROBIAL SKIN FRICTION AND MOISTURE CONTROL FABRIC, GYNAECOLOGY AND CONTINENCE CARE PRODUCTS

Has been assessed with respect to:

the conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:

Høvik, 5 March 2021

For the issuing office:

Notified Body 2460

DNV Product Assurance AS

Check Validity




Eugenie Winger Husebye
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance Norway AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f3, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM -410 to DNV GL Presafe A/S (NB2460)	7 December 2020
1.0	Corrected validity end date in Spanish certificate No. 10000410284-PA-NA-DNK Correction of identification no. in certificate no. 10000423477-PA-NA-DNK	5 March 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Debridement products	Wound Debridement pad	Is
Bags for fluid drainage	Wound and fistula Drainage Bags	Is
Urinary Catheters for intermittent use	Urinary drainage catheters for intermittent use Urinary infusion and drainage catheters for intermittent use Dilation Catheters for intermittent use	Is
Devices for Surgical drainage, collect and dilation	Bulb for Drain Dilating Bougies EasiVac bladder evacuator	Is
Ostomy bags	Ostomy Post-Operative bags	Is
Bags for urinary drainage and collection	Urine Bags	Is
Pushers, connectors, dilators, introducer for urology	Catheter Valve Steerable pusher	Is

	Connectors FREUDENBERG introducer Luer connector for urine bag Non steerable pusher Tuohy Borst Adapter Urethral bougie Ureteral dilator	
Urological catheters	Ureteric Catheter for R.U.P. PHILIPS Catheter, 1 Eye Female Metric Thread Prostatic measuring catheter	Is
Ostomy bags with refeeding	Ostomy bags (refeeding)	Ila
Surgical ostomy devices	Ostomy rod	Ila
Devices for extraction of stones	Urinary stone extractors Biliary stone extractors	Ila
Devices for biopsy	Biopsy guns	Ila
Suction-irrigation devices	Suction-irrigation devices	Ila
Surgical drainage	Simple drainage Suction drainage Biliary drainage	Ila
Suture/Needle Passer	Introducers	Ila
Urinary catheters	Urinary Indwelling Catheters Urinary/Percutaneous Indwelling Catheters Urethral catheter without balloon	Ila

Urodynamic measurement devices	Urodynamic catheters	Ila
Ureteral implants for urology	Double loop ureteral stents	Ila
Connector for tube and for suction-irrigation device	Connector	Ila
Catheter for organ procurement	Multi-organ procurement catheter	Ila
Ureteral devices	Ureteral balloon dilatation catheter Ureteral access sheath Ureteral access sheath with ureteral dilator Ureteric catheter Occlusion balloon catheter	Ila
Devices for bladder injection	Needle for bladder injection	Ila
Devices for renal percutaneous access	Percutaneous balloon dilatation catheter Amplatz sheath Percutaneous dilator Percutaneous needle PCN fixation disc	Ila
Guidewires	PTFE coated Seldinger guidewire Schüller guidewire Lunderquist guidewire Hydrophilic guidewire	Ila
Wound dressings and gels	Biatain Foam Wound Dressings Comfeel Hydrocolloid Wound Dressings Hydrocapillary Wound Dressings Gelling Fiber Wound Dressing Physiotulle Dressings	IIb

	Purilon Wound Hydrogel	
Gels for anal use	Anal Gel for Anal Plugs	IIb
Plugs for body orifices	Ostomy Plugs Anal plugs	IIb
Penile implants	Penile Inflatable Implants Penile Rigidity Implants	IIb
Urinary Catheters	Urinary Indwelling Catheters Urinary/Percutaneous Indwelling Catheters Urinary/Suprapubic Indwelling Catheters	IIb
Naso Gastric & Naso Intestinal devices	Gastro-intestinal tube	IIb
Surgical Meshes	Virtue Male Sling System	IIb
Ureteral, urethral bypass and prostatic implants for urology	Double loop ureteral stents Ureteral bypass Prostatic stents Urethral stent	IIb
Antibacterial Foam Dressings	Biatain Ag Adhesive Biatain Ag Non-Adhesive Biatain Ag Filler/Cavity Biatain Silicone Ag	III*
Antimicrobial skin friction and moisture control fabric	Interdry	III*
Ibu Foam Dressings	Biatain Ibu Soft-Hold Biatain Ibu Non-Adhesive	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.:

- 10000410284-PA-NA-DNK - Rev 1.0
- 10000423477-PA-NA-DNK - Rev 1.0
- 10000423479-PA-NA-DNK - Rev 0.0

Sites covered by this certificate

Site Name	Address
Sites in Denmark	
Coloplast A/S	Aa. Louis-Hansens Allé 15, Mørdrup, 3060 Espergaerde
	Holtedam 1 and 3, 3050 Humlebaek
Sites in France	
Coloplast Manufacturing France SAS	9 Avenue Edmond Rostand, CS 70218, 24206 Sarlat-la- canéda Credex
	20, rue Blaise Pascal, 24200 Sarlat-la-canéda
	Lieudit La Boursidière, Centre d’Affaires, 92350 Le Plessis Robinson
	ZAC du Clotais, 2b, Route du Chemin Blanc, 91160 Champlan
Sites in Hungary	
Coloplast Hungary KFT	Búzavirág út 15, 2800 Tatabánya
	Coloplast utca 2, 4300 Nyírbátor
	Kerék utca 3, 2800 Tatabánya
Sites in USA	
Coloplast Corporation	1601 West River Road North, Minneapolis, MN 55411
Coloplast Manufacturing US, LLC	1601 West River Road North, Minneapolis, MN 55411

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Place and date: Høvik, 5 March 2021

Coloplast Manufacturing US, LLC	1940 Commerce Dr. North Mankato, MN 56003
Sites in People's Republic of China	
Coloplast (China) Ltd.	No. 202, Baocheng Rd, Xiangzhou District, Zhuhai 519030
	No. 18 Pingbei Er Rd., Nanping Industrial Park, Zhuhai City 519060
Sites in Costa Rica	
Coloplast Volume Mfg. Costa Rica SA	Calle 58, Zona Franca La Lima, La Lima, Guadalupe, 30106 Cartago

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. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

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

Conformity declaration and marking of product

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

End of Certificate