

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
10000410282-PA-NA-DNK - Rev 0.0

Project No.:  
PRJN-199515-2020-PA-DNK

Valid Until:  
21 September 2023

This is to certify that the quality system of:

### Coloplast A/S

Holtedam 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, 7 December 2020

For:  
DNV GL PRESAFE AS  
Notified Body No.: 2460



Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



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## 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

## 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 Connectors FREUDENBERG introducer Luer connector for urine bag Non steerable pusher Tuohy Borst Adapter Urethral bougie Ureteral dilator	Is
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)	IIa
Surgical ostomy devices	Ostomy rod	IIa
Devices for extraction of stones	Urinary stone extractors Biliary stone extractors	IIa

Certificate No.:  
10000410282-PA-NA-DNK - Rev 0.0

Project No.:  
PRJN-199515-2020-PA-DNK

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Devices for biopsy	Biopsy guns	IIa
Suction-irrigation devices	Suction-irrigation devices	IIa
Surgical drainage	Simple drainage Suction drainage Biliary drainage	IIa
Suture/Needle Passer	Introducers	IIa
Urinary catheters	Urinary Indwelling Catheters Urinary/Percutaneous Indwelling Catheters Urethral catheter without balloon	IIa
Urodynamic measurement devices	Urodynamic catheters	IIa
Ureteral implants for urology	Double loop ureteral stents	IIa
Connector for tube and for suction-irrigation device	Connector	IIa
Catheter for organ procurement	Multi-organ procurement catheter	IIa
Ureteral devices	Ureteral balloon dilatation catheter Ureteral access sheath Ureteral access sheath with ureteral dilator Ureteric catheter Occlusion balloon catheter	IIa
Devices for bladder injection	Needle for bladder injection	IIa
Devices for renal percutaneous access	Percutaneous balloon dilatation catheter Amplatz sheath Percutaneous dilator Percutaneous needle PCN fixation disc	IIa
Guidewires	PTFE coated Seldinger guidewire Schüller guidewire Lunderquist guidewire Hydrophilic guidewire	IIa
Wound dressings and gels	Biatain Foam Wound Dressings Comfeel Hydrocolloid Wound Dressings Hydrocapillary Wound Dressings Gelling Fiber Wound Dressing Physiotulle Dressings Purilon Wound Hydrogel	IIb
Gels for anal use	Anal Gel for Anal Plugs	IIb
Plugs for body orifices	Ostomy Plugs Anal plugs	IIb
Penile implants	Penile Inflatable Implants	IIb

Certificate No.:  
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Project No.:  
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	Penile Rigidity Implants	
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 0.0
- 10000423477-PA-NA-DNK - Rev 0.0
- 10000423479-PA-NA-DNK - Rev 0.0

The complete list of devices is filed with the Notified Body

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**Sites covered by this certificate**

Site Name	Address
<b>Sites in Denmark</b>	
Coloplast A/S	Aa. Louis-Hansens Allé 15, Mørdrup, 3060 Espergaerde
	Holtedam 1 and 3, 3050 Humlebaek
<b>Sites in France</b>	
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
<b>Sites in Hungary</b>	
Coloplast Hungary KFT	Búzavirág út 15, 2800 Tatabánya
	Coloplast utca 2, 4300 Nyírbátor
	Kerék utca 3, 2800 Tatabánya
<b>Sites in USA</b>	
Coloplast Corporation	1601 West River Road North, Minneapolis, MN 55411
Coloplast Manufacturing US, LLC	1601 West River Road North, Minneapolis, MN 55411
Coloplast Manufacturing US, LLC	1940 Commerce Dr. North Mankato, MN 56003
<b>Sites in People’s Republic of China</b>	
Coloplast (China) Ltd.	No. 202, Baocheng Rd, Xiangzhou District, Zhuhai 519030
	No. 18 Pingbei Er Rd., Nanping Industrial Park, Zhuhai City 519060
<b>Sites in Costa Rica</b>	
Coloplast Volume Mfg. Costa Rica SA	Calle 58, Zona Franca La Lima, La Lima, Guadalupe, 30106 Cartago

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## 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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate