

Quality System Certificate

Certificate No.:
DGM – 639

Reference:
auriso2109v2130f492

Date of issue:
2021-09-08

Valid Until:
2024-09-08

Initial date of issue:
2008-09-23

This is to certify that the quality system of:

Coloplast A/S
Holtedam 1
3050 Humlebaek
Denmark

fulfills the requirements in:

**ISO 9001:2015, DS/EN ISO 9001:2015,
DS/EN ISO 13485:2016, EN ISO 13485:2016 and ISO 13485:2016**

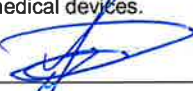
The certificate covers the following activities:

Design and manufacturing of stents, implants, irrigation and drainage devices, catheters, penile prosthesis, testicular prosthesis, surgical meshes, intravesical needles, surgical instruments, anal plugs, external catheters and urine bags, ostomy appliances, wound dressings, skin care products and accessories for the areas of surgery, urology, gynecology and continence care, ostomy care, wound and skin care.

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001:2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S

Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark



Zeshaan Sayd
Authorized person

For Presafe Denmark A/S

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Additional site(s) covered by the certificate:

Sites in Denmark

Coloplast A/S
Holtedam 1 and 3
3050 Humlebaek
Denmark

Coloplast A/S
Aa. Louis-Hansens Allé 15
Mørdrup
3060 Espergaerde
Denmark

Sites in France

Coloplast Manufacturing France SAS
9 Avenue Edmond Rostand
CS 70218
24206 Sarlat-la-Canéda Cedex
France

Coloplast Manufacturing France SAS
Lieudit La Boursidière
Centre d'Affaires
92350 Le Plessis Robinson
France

Coloplast Manufacturing France SAS
20, rue Blaise Pascal
24200 Sarlat La Canéda
France

Coloplast Manufacturing France SAS
ZAC du Clotais
2b, Route du Chemin Blanc
91160 Champlan
France

Laboratoires Coloplast S.A.S
35 bvd de Courcerin
77185 Lognes
France

Sites in Hungary

Coloplast Hungary KFT
Búzavirág út 15
2800 Tatabánya
Hungary

Coloplast Hungary KFT
Coloplast utca 2
4300 Nyírbátor
Hungary

Coloplast Hungary KFT
Kerek utca 3
2800 Tatabánya
Hungary

Coloplast Hungary KFT
Kerek utca 4
2800 Tatabánya
Hungary

Sites in USA

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 US, LLC
1940 Commerce Dr.
North Mankato, MN 56003
USA

Coloplast Manufacturing US, LLC
475 Riverside Pkwy.
Suite 400
Lithia Springs, GA 30122
USA

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Sites in People's Republic of China

Coloplast (China) Ltd.
No. 202, Baocheng Rd
Xiangzhou District
Zhuhai 519030
China

Coloplast (China) Ltd.
No. 18 Pingbei Er Rd.
Nanping Industrial Park
Zhuhai City 519060
China

Site(s) in Costa Rica

Coloplast Volume Mfg. Costa Rica SA
Calle 58, Zona Franca La Lima
La Lima
Guadalupe
30106 Cartago
Costa Rica

Site(s) in Italy

Coloplast S.p.A
Via del Commercio Associato 15
40127 Bologna
Italy

Site(s) in Spain

Coloplast Productos Medicos, S.A.
Arroyo de los Prados, 5
Polígono Industrial las Arenas
28320 Pinto – Madrid
Spain

Site(s) in Sweden

Coloplast AB
Energigatan 21
434 37 Kungälv
Sweden

Site(s) in United Kingdom

Coloplast Ltd
Unit 2, Artemis Way Alwalton Hill
Peterborough
PE73FU
United Kingdom

Site(s) in Germany

Coloplast Distribution GmbH
Werner-Schröder-Strasse 1
21035 Hamburg
Germany