Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN: DK-MF-000025526
EU Product Classification according to Annex VIII	IIb Rule Number: 8
Intended Purpose	Cystodrain integral sets are intended to be used for: - Supra-pubic drainage of the urinary bladder. - Bladder instillation of physiological saline solution by the supra-pubic route. - Replacement of supra-pubic drainage catheter (only for replacement sets).
Basic UDI-DI	57089326358828U
Conformity Assessment Procedure	Annex IX
Notified Body Name and Number	DNV Product Assurance AS - (2460)
Notified Body Certificate Type and Number	EU Quality Management System Certificate - 10000376655-PA-NoMA-DNK
Conformity to Common Specification(s)	No relevant Common Specification to list
Conformity to other Union Legislation(s)	No relevant Union Legislation to list

This EU Declaration of Conformity is applicable for following catalogue numbers:

Catalogue Number	Product Name	Original CE Marking Date yyyy-mm-dd
CD1B18	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1012	Cystodrain Integral Supra-pubic drainage set	2003-07-17
CD1A10	Cystodrain Integral Supra-pubic catheter replacement set with guidewire	2003-07-17
CD1014	Cystodrain Integral Supra-pubic drainage set	2003-07-17
CD1210	Cystodrain Integral Supra-pubic drainage set	2003-07-17
CD1C10	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1B10	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1214	Cystodrain Integral Supra-pubic drainage set	2003-07-17
CD1A12	Cystodrain Integral Supra-pubic catheter replacement set with guidewire	2003-07-17
CD1A14	Cystodrain Integral Supra-pubic catheter replacement set with guidewire	2003-07-17
CD1C20	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1B20	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1B14	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1010	Cystodrain Integral Supra-pubic drainage set	2003-07-17
CD1A16	Cystodrain Integral Supra-pubic catheter replacement set with guidewire	2003-07-17
CD1C12	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1C14	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1B12	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1C16	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1B16	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1114	Cystodrain Integral Dilation set for supra-pubic drainage	2003-07-17
CD1C18	Cystodrain Integral Supra-pubic catheter replacement set	2003-07-17
CD1212	Cystodrain Integral Supra-pubic drainage set	2003-07-17
CD1112	Cystodrain Integral Dilation set for supra-pubic drainage	2003-07-17

This EU Declaration of Conformity is issued under the sole responsibility of Coloplast A/S. Coloplast A/S declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

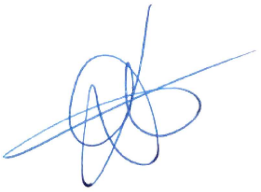
Date of signature: 2025-02-13

yyyy-mm-dd

Place of signature: Le Plessis-Robinson, France

Place, Country

Signed on behalf of Coloplast A/S:



FRSDR, Sihem Darraji, Senior Director, Global Regulatory Affairs

Name, Title