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	I Rule Number: 1
Intended Purpose	Brava Barrier Cream is intended for protection of intact skin around the stoma exposed to intestinal contents, urine and pus.
Basic UDI-DI	57089322976779M
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
12001/120010	Brava Barrier Cream	2014-03-21
12000/120001/120005	Brava Barrier Cream	2010-01-15

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: 2023-09-13

yyyy-mm-dd

Place of signature: Humlebaek, Denmark

Place, Country

DKBENB, Benedikte Blom, Head of Regulatory Affairs

Signed on behalf of Coloplast A/S:

Name, Title