

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	Powder is intended for moisture absorption on intact peristomal skin.	
Basic UDI-DI	57089322976759H	
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
1914 / 019140 / 01914	Brava Powder	2015-03-05
1907 / 019070 / 19070 / 01907	Coloplast Ostomy Powder	2004-10-28
1907 / 19075 / 01907 / 019075	Brava Powder	2004-10-28

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: 2024-01-24

yyyy-mm-dd

Place of signature: Humlebaek, Denmark

Place, Country

DKBENB, Benedikte Blom, Director of Regulatory Affairs, Chronic Care

Signed on behalf of Coloplast A/S:

Name, Title

Belledikte Blom