

Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
Product Name	Brava Protective Seal
EU Product Classification according to Annex VIII	I Rule Number: 1
Intended Purpose	Brava Protective Seal is intended to provide a seal between intact peristomal skin and ostomy base plate, thereby protecting the skin against stoma output. The product is designed to fill out cavities/folds in the peristomal skin.
Basic UDI-DI	57089322976929H
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	Product Description	Original CE Marking Date yyyy-mm-dd
12049 / 120492 / 120491 / 120490	Brava Protective Seal	Thickness 4.2 mm Diameter Inner 34 mm Diameter Outer 64 mm	2016-05-17
12037 / 120370	Brava Protective Seal	Thickness 2.5 mm Diameter Inner 27 mm Diameter Outer 57 mm	2016-05-17
12047 / 120470	Brava Protective Seal	Thickness 4.2 mm Diameter Inner 27 mm Diameter Outer 57 mm	2016-05-17
120350 / 12035 / 120351 / 120352	Brava Protective Seal	Thickness 2.5 mm Diameter Inner 18 mm Diameter Outer 48 mm	2016-05-17
12045 / 120451 / 120452 / 120450	Brava Protective Seal	Thickness 4.2 mm Diameter Inner 18 mm Diameter Outer 48 mm	2016-05-17
12039 / 120390 / 120392 / 120391	Brava Protective Seal	Thickness 2.5 mm Diameter Inner 34 mm Diameter Outer 64 mm	2016-05-17
12038 / 120380 / 120381 / 120382	Brava Protective Seal	Thickness 2.5 mm Diameter Inner 18 mm Diameter Outer 64 mm	2018-10-01
120460 / 12046	Brava Protective Seal	Thickness 4.2 mm Diameter Inner 18 mm Diameter Outer 57 mm	2018-10-01
12036 / 120360	Brava Protective Seal	Thickness 2.5 mm Diameter Inner 18 mm Diameter Outer 57 mm	2018-10-01
12048 / 120480 / 120481 / 120482	Brava Protective Seal	Thickness 4.2 mm Diameter Inner 18 mm Diameter Outer 64 mm	2018-10-01
12032 / 120320 / 120321	Brava Protective Seal	Thickness 2.5 mm Diameter Inner 18 mm Diameter Outer 76 mm	2019-06-12
12033 / 120330	Brava Protective Seal	Thickness 2.5 mm Diameter Inner 27 mm Diameter Outer 76 mm	2019-06-12

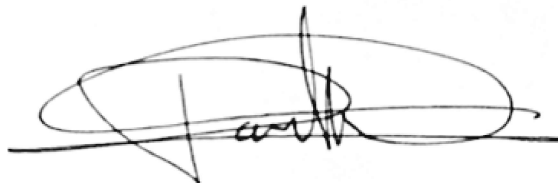
This EU Declaration of Conformity is issued under the sole responsibility of Coloplast A/S. Coloplast A/S declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and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

Date of signature: 2021-05-07
yyyy-mm-dd

Place of signature: Humlebaek, Denmark
Place, Country

DKBERO, Benjamin Rochette, Vice President, Global Regulatory Affairs

Signed on behalf of Coloplast A/S:

A handwritten signature in black ink, appearing to be 'B. Rochette', written over a horizontal line. The signature is stylized and somewhat cursive.

Name, Title