

Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
Product Name	Conveen Optima
EU Product Classification according to Annex VIII	I Rule Number: 1
Intended Purpose	Urisheaths are intended to drain urine, normally into a urinary collection bag.
Basic UDI-DI	570893229784098
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
22135 / 221359 / 221350	Conveen Optima	2005-04-12
22125 / 221250 / 221259	Conveen Optima	2005-04-12
220300 / 22030 / 220309	Conveen Optima	2005-04-12
22121 / 221219 / 221210	Conveen Optima	2005-04-12
22028 / 220280 / 220289	Conveen Optima	2015-05-28
22130 / 221300 / 221309	Conveen Optima	2005-04-12
220250 / 22025 / 220259	Conveen Optima	2005-04-12
220350 / 22035 / 220359	Conveen Optima	2005-04-12
220400 / 22040 / 220409	Conveen Optima	2005-04-12
21130	Conveen Optima	2005-04-12
21135	Conveen Optima	2005-04-12
21140	Conveen Optima	2005-04-12
21125	Conveen Optima	2005-04-12

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:

2021-05-12

yyyy-mm-dd

Place of signature:

Humblebaek, Denmark

Place, Country

DKBERO, Benjamin Rochette, Vice President, Global Regulatory Affairs

Signed on behalf of Coloplast A/S:

A handwritten signature in blue ink, consisting of a large, stylized loop followed by a series of smaller, more intricate strokes.

Name, Title