

Declaration of Conformity to EU Medical Device Regulation 2017/745

Legal Manufacturer	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN:
EU Product Classification according to Annex VIII	I Rule Number: 1
Intended Purpose	The adhesive baseplate is attached to the ostomy bag and is intended to adhere to intact skin around the stoma.
Basic UDI-DI	57089322976108M
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
14291 / 142910	Assura/Alterna Ostomy baseplate	2005-02-28
14292 / 142920	Assura/Alterna Ostomy baseplate	2005-02-28
12707 / 127070	Assura/Alterna Ostomy baseplate	2001-02-19
12725	Assura/Alterna Ostomy baseplate	2001-02-19
14298 / 142980	Assura/Alterna Ostomy baseplate	2005-02-28
12719 / 127190	Assura/Alterna Ostomy baseplate	2001-02-19
46767 / 467670	Assura/Alterna Ostomy baseplate	2001-02-19
14293 / 142930	Assura/Alterna Ostomy baseplate	2005-02-28
12704 / 127040	Assura/Alterna Ostomy baseplate	2001-02-19
14275 / 142750	Assura/Alterna Ostomy baseplate	2001-10-23
14294 / 142940	Assura/Alterna Ostomy baseplate	2005-02-28
14296 / 142960	Assura/Alterna Ostomy baseplate	2005-02-28
12727	Assura/Alterna Ostomy baseplate	2001-02-19
14262 / 142621 / 142620	Assura/Alterna Ostomy baseplate	2001-10-23
14249 / 142490	Assura/Alterna Ostomy baseplate	2001-12-14
12701 / 127010	Assura/Alterna Ostomy baseplate	2001-02-19
14237	Assura/Alterna Ostomy baseplate	2001-12-14
14295 / 142950	Assura/Alterna Ostomy baseplate	2005-02-28
127080 / 12708	Assura/Alterna Ostomy baseplate	2001-02-19
14261 / 142610 / 142611	Assura/Alterna Ostomy baseplate	2001-10-23
14272 / 142720	Assura/Alterna Ostomy baseplate	2001-10-23
14271 / 142710	Assura/Alterna Ostomy baseplate	2001-10-23

12724	Assura/Alterna Ostomy baseplate	2001-02-19
14283 / 142830	Assura/Alterna Ostomy baseplate	2005-02-28
14297 / 142970	Assura/Alterna Ostomy baseplate	2005-02-28
14263 / 142630 / 142631	Assura/Alterna Ostomy baseplate	2001-10-23
12728	Assura/Alterna Ostomy baseplate	2001-02-19
12709 / 127090	Assura/Alterna Ostomy baseplate	2001-02-19
12702 / 127020	Assura/Alterna Ostomy baseplate	2001-02-19
467550 / 46755	Assura/Alterna Ostomy baseplate	2001-02-19
14277 / 142770	Assura/Alterna Ostomy baseplate	2001-10-23
12722	Assura/Alterna Ostomy baseplate	2001-02-19
14282 / 142820	Assura/Alterna Ostomy baseplate	2005-02-28
467660 / 46766	Assura/Alterna Ostomy baseplate	2001-02-19
46759 / 467590	Assura/Alterna Ostomy baseplate	2001-02-19
14274 / 142740	Assura/Alterna Ostomy baseplate	2001-10-23
46765 / 467650	Assura/Alterna Ostomy baseplate	2001-02-19
46769 / 467690 / 467691	Assura/Alterna Ostomy baseplate	2001-02-19
12723	Assura/Alterna Ostomy baseplate	2001-02-19
467570 / 46757	Assura/Alterna Ostomy baseplate	2001-02-19
14281 / 142810	Assura/Alterna Ostomy baseplate	2005-02-28
14273 / 142730	Assura/Alterna Ostomy baseplate	2001-10-23
14246 / 142460	Assura/Alterna Ostomy baseplate	2001-12-14
46756 / 467560	Assura/Alterna Ostomy baseplate	2001-02-19
142780 / 14278	Assura/Alterna Ostomy baseplate	2001-10-23
12716 / 127160	Assura/Alterna Ostomy baseplate	2001-02-19
12703 / 127030	Assura/Alterna Ostomy baseplate	2001-02-19
14236 / 142360	Assura/Alterna Ostomy baseplate	2001-12-14
12705 / 127050	Assura/Alterna Ostomy baseplate	2001-02-19
12726	Assura/Alterna Ostomy baseplate	2001-02-19
14243 / 142430	Assura/Alterna Ostomy baseplate	2001-12-14
46747 / 467470	Assura/Alterna Ostomy baseplate	2001-02-19
12717	Assura/Alterna Ostomy baseplate	2001-02-19
46746 / 467461 / 467460	Assura/Alterna Ostomy baseplate	2001-02-19
127060 / 12706	Assura/Alterna Ostomy baseplate	2001-02-19
12729	Assura/Alterna Ostomy baseplate	2001-02-19
14276 / 142760	Assura/Alterna Ostomy baseplate	2001-10-23
14239	Assura/Alterna Ostomy baseplate	2001-12-14
12718	Assura/Alterna Ostomy baseplate	2001-02-19
14235 / 142350	Assura/Alterna Ostomy baseplate	2001-12-14
14234 / 142340	Assura/Alterna Ostomy baseplate	2001-12-14
467450 / 46745	Assura/Alterna Ostomy baseplate	2001-02-19
14233 / 142330	Assura/Alterna Ostomy baseplate	2001-12-14
14232 / 142320	Assura/Alterna Ostomy baseplate	2001-12-14
12721	Assura/Alterna Ostomy baseplate	2001-02-19

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: 2022-09-28

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