

## Declaration of Conformity to EU Medical Device Regulation 2017/745

<b>Legal Manufacturer</b>	Coloplast A/S Holtedam 1, 3050 Humlebaek, DK SRN: DK-MF-000025526
<b>EU Product Classification according to Annex VIII</b>	IIb Rule Number: 8
<b>Intended Purpose</b>	<ul style="list-style-type: none"> <li>• Bladder drainage by urethral catheterization, or by suprapubic catheterization (only for non-grooved, straight 2-way Folyzil catheters with a maximum balloon volume of 15mL).</li> <li>• Bladder instillation of physiological saline solution.</li> <li>• Post-operative bladder irrigation-lavage by urethral catheterization (only for 3-way Folyzil catheters for neobladder).</li> </ul>
<b>Basic UDI-DI</b>	57089326358748V
<b>Conformity Assessment Procedure</b>	Annex IX
<b>Notified Body Name and Number</b>	DNV Product Assurance AS - (2460)
<b>Notified Body Certificate Type and Number</b>	EU Quality Management System Certificate - 10000376655-PA-NoMA-DNK
<b>Conformity to Common Specification(s)</b>	No relevant Common Specification to list
<b>Conformity to other Union Legislation(s)</b>	No relevant Union Legislation to list

This EU Declaration of Conformity is applicable for following catalogue numbers:

<b>Catalogue Number</b>	<b>Product Name</b>	<b>Original CE Marking Date yyyy-mm-dd</b>
AA6106	Folyzil® Silicone Foley catheter	1999-12-20
AA6108	Folyzil® Silicone Foley catheter	1999-12-20
AA6110	Folyzil® Silicone Foley catheter	1999-12-20
AA6112	Folyzil® Silicone Foley catheter	1998-01-15
AA6114	Folyzil® Silicone Foley catheter	1998-01-15
AA6116	Folyzil® Silicone Foley catheter	1998-01-15
AA6118	Folyzil® Silicone Foley catheter	1998-01-15
AA6120	Folyzil® Silicone Foley catheter	1998-01-15
AA6122	Folyzil® Silicone Foley catheter	1998-01-15
AA6124	Folyzil® Silicone Foley catheter	1998-01-15
AA6308	Folyzil® Silicone Foley catheter	1998-01-15
AA6310	Folyzil® Silicone Foley catheter	1998-01-15
AA6312	Folyzil® Silicone Foley catheter	1998-01-15
AA6314	Folyzil® Silicone Foley catheter	1998-01-15
AA6316	Folyzil® Silicone Foley catheter	1998-01-15
AA6318	Folyzil® Silicone Foley catheter	1998-01-15

AA6320	Folysil® Silicone Foley catheter	1998-01-15
AA6322	Folysil® Silicone Foley catheter	1998-01-15
AA6324	Folysil® Silicone Foley catheter	1998-01-15
AA6408	Folysil® Silicone Foley catheter	1998-01-15
AA6410	Folysil® Silicone Foley catheter	1998-01-15
AA6412	Folysil® Silicone Foley catheter	1998-01-15
AA6414	Folysil® Silicone Foley catheter	1998-01-15
AA6416	Folysil® Silicone Foley catheter	1998-01-15
AA6418	Folysil® Silicone Foley catheter	1998-01-15
AA6420	Folysil® Silicone Foley catheter	1998-01-15
AA6422	Folysil® Silicone Foley catheter	1998-01-15
AA6424	Folysil® Silicone Foley catheter	1998-01-15
AA6820	Folysil® Silicone Foley catheter	1998-01-15
AA6822	Folysil® Silicone Foley catheter	1998-01-15
AA6C18	Folysil® Silicone Foley catheter	1998-01-15
AA6C20	Folysil® Silicone Foley catheter	1998-01-15
AA6C22	Folysil® Silicone Foley catheter	1998-01-15
AA6C24	Folysil® Silicone Foley catheter	1998-01-15
AA6406	Folysil® Silicone Foley catheter	1998-01-15
AA6516	Folysil® Silicone Foley catheter	1998-01-15
AA6520	Folysil® Silicone Foley catheter	1998-01-15
AA9320	Folysil® Silicone Foley catheter	2004-10-01
AA9314	Folysil® Silicone Foley catheter	2004-10-01
AA6622	Folysil® Silicone Foley catheter	1998-01-15
AA6512	Folysil® Silicone Foley catheter	1998-01-15
AA6918	Folysil® Silicone Foley catheter	2000-09-07
AA6524	Folysil® Silicone Foley catheter	1998-01-15
AA6522	Folysil® Silicone Foley catheter	1998-01-15
AA9316	Folysil® Silicone Foley catheter	2004-10-01
AA6514	Folysil® Silicone Foley catheter	1998-01-15
AA6618	Folysil® Silicone Foley catheter	1998-01-15
AA6920	Folysil® Silicone Foley catheter	2000-09-07
AA6922	Folysil® Silicone Foley catheter	2000-09-07
AA6614	Folysil® Silicone Foley catheter	1998-01-15
AA9312	Folysil® Silicone Foley catheter	2004-10-01
AA9318	Folysil® Silicone Foley catheter	2004-10-01
AA6612	Folysil® Silicone Foley catheter	1998-01-15
AA6518	Folysil® Silicone Foley catheter	1998-01-15
AA9322	Folysil® Silicone Foley catheter	2004-10-01
AA6624	Folysil® Silicone Foley catheter	1998-01-15
AA6616	Folysil® Silicone Foley catheter	1998-01-15
AA6620	Folysil® Silicone Foley catheter	1998-01-15
HA6120	Folysil® Silicone Foley catheter	1998-01-15

HI6616	Folysil® Silicone Foley catheter	2014-10-30
HS6118	Folysil® Silicone Foley catheter	2003-09-30
HI6620	Folysil® Silicone Foley catheter	2014-10-30
HA6108	Folysil® Silicone Foley catheter	1999-12-20
HA6114	Folysil® Silicone Foley catheter	1998-01-15
HA6118	Folysil® Silicone Foley catheter	1998-01-15
HS6122	Folysil® Silicone Foley catheter	2003-09-30
HS6116	Folysil® Silicone Foley catheter	2003-09-30
HA6124	Folysil® Silicone Foley catheter	1998-01-15
HA6110	Folysil® Silicone Foley catheter	1999-12-20
HS6120	Folysil® Silicone Foley catheter	2003-09-30
HS6112	Folysil® Silicone Foley catheter	2003-09-30
HI6622	Folysil® Silicone Foley catheter	2014-10-30
HS6114	Folysil® Silicone Foley catheter	2003-09-30
HA6112	Folysil® Silicone Foley catheter	1998-01-15
HA6106	Folysil® Silicone Foley catheter	1999-12-20
HS6124	Folysil® Silicone Foley catheter	2003-09-30
HA6116	Folysil® Silicone Foley catheter	1998-01-15
HI6624	Folysil® Silicone Foley catheter	2014-10-30
HI6614	Folysil® Silicone Foley catheter	2014-10-30
HA6122	Folysil® Silicone Foley catheter	1998-01-15
HI6612	Folysil® Silicone Foley catheter	2014-10-30
HI6618	Folysil® Silicone Foley catheter	2014-10-30

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.

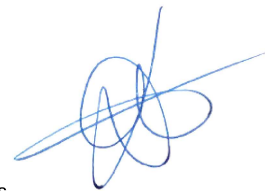
Date of signature: 2024-04-09

yyyy-mm-dd

Place of signature: Le Plessis-Robinson, France

Place, Country

Signed on behalf of Coloplast A/S:



FRSDR, Sihem Darraji, Senior Director, Global Regulatory Affairs

Name, Title