

# Medical Device EU Declaration of Conformity

## EU Declaration of Conformity Annex IV of Medical Device Regulation (EU) 2017/745

The EU Declaration of Conformity is issued under the sole responsibility of CMC Hygea Ltd.

<b>MDR Classification Rule</b>	Class 1 Medical Device under Rule 1	
<b>Product Supplier</b>	CMC Hygea Ltd.	
<b>Supplier Address</b>	Unit 630G, Northern Extension, IDA Industrial Park, Cleaboy Road, Waterford, Ireland X91HY58	
<b>Product Code</b>	<b>Basic UDI-DI</b>	<b>Product Trade Name &amp; Description</b>
CMCP 10001A	539152805000CA	PathAguard ABLiS Basin
CMCL 10001A	539152805001CC	PathAguard ABLiS Basin Liner
CMCD 10001A	539152805002CE	PathAguard ABLiS Liner Dispenser
CMCBC 10001A	539152805006CN	PathAguard ABLiS Basin Carrier
<b>Intended Purpose</b>	PathAguard ABLiS System is intended for use to bath/wash the patients at the bed side or elsewhere whilst reducing the risk of cross contamination for the patient and healthcare assistance.	
CMC Hygea Limited declares that device(s) listed above conforms to the relevant provisions of the Medical Device Regulation (EU) 2017/745 dated 5 <sup>th</sup> April 2017 and is in accordance with Annex IV, as implemented by the European Union's Medical Devices Regulations.		
<b>Person Responsible Signature:</b> Michael Malone Chief Executive Officer CMC Hygea Ltd. Unit 630G, Northern Extension, IDA Industrial Park, Cleaboy Road, Waterford, Ireland X91HY58		
<b>Date of Issue:</b>	13 <sup>th</sup> Mar 2023	
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