

## EU DECLARATION OF CONFORMITY

**Manufacturer name and address:** Precision Dippings Manufacturing Ltd t/a Bloccs, Unit J, Lawrence Drive, Yate Bristol BS37 5PG

**SRN (Single Registration Number):** GB-MF-000014092

**Authorized Representative name and address (if applicable):** Obelis s.a.  
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We, Precision Dippings manufacturing Ltd t/a Bloccs, hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745.

The device(s) is/are Class 1 following Rule 4 of Annex VIII of Regulation (EU) 2017/745.

The following conformity assessment procedure has been performed as per Article 52 and against the applicable requirements of Clause 7 for Class 1 devices and (where relevant) the following CE certificate(s) with reference to the attached schedule of produced devices, named as:

### **Waterproof Cast and Dressing Cover.**

*The following Standards have been used and in relation to which conformity is declared:*

Regulation (EU) 2017/745 (as stated with the above scope)

Quality Management System Certification ISO 9001: 2015 (British Standards Institute)

We hereby also declare under our sole responsibility that the device(s) listed in the attached schedule comply(ies) with the provisions of Regulation (EU) 2017/745. Our registration within the UK, MHRA is based on the declaration dated 25 July 2013 on the RG2 form and means that:

### **For Manufacturers of Class I medical devices, Assemblers, and Sterilisers**

Issue place and date: Bristol 30/03/2022

Kate Richards (Director)



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Attachments – DoC MDR – ID # 00060320 – V1 – 21/03/2021 +44 (0) 1454 318004

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## Annex - List of Devices Covered by the Declaration of Conformity

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#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/EMDN code
1	Waterproof Cast and Dressing Cover	AEP86-L AEP86-M AEP86-S AFA72 AFL76 AKP87-L AKP87-M AKP87-S AKP87-XL ASA70 ASL74 CEP86-L CEP85-M CEP85-S CEP85-XS CFA73-L CFA73-M CFA73-S CFA73-XS CFL77-L CFL77-M CFL77-S CSA71-L CSA71-M CSA71-S CSL75-L CSL75-M CSL75-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	5060295748BLO5212M	