

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

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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 schule comply(ies) with the provisions of Regulation (EU) 2017/745. Our registration withiin 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 19/05/2021

Kate Richards (Director)

Precision Dippings Manufacturing Ltd t/a Bloccs.

Unit J, Lawrence Drive, Yate, Bristol BS37 5PG

Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/EMDN code
1	Bloccs waterproof cover- Adult Elbow - S	AEP86-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
2	Bloccs waterproof cover- Adult Elbow - M	AEP86-M	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
3	Bloccs waterproof cover- Adult Elbow - L	AEP86-L	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
4	Bloccs waterproof cover- Adult Full Arm	AFA72	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
5	Bloccs waterproof cover- Adult Full Leg	AFL76	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
6	Bloccs waterproof cover- Adult Knee - L	AKP87-L	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
7	Bloccs waterproof cover- Adult Knee - M	AKP87-M	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
8	Bloccs waterproof cover- Adult Knee - S	AKP87-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
9	Bloccs waterproof cover- Adult Knee - XL	AKP87-XL	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
10	Bloccs waterproof cover- Adult Short Arm	ASA70	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
11	Bloccs waterproof cover- Adult Short Leg	ASL74	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
12	Bloccs waterproof cover- Child Elbow - L	CEP85-L	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
13	Bloccs waterproof cover- Child Elbow - M	CEP85-M	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	

14	Bloccs waterproof cover- Child Elbow - S	CEP85-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
15	Bloccs waterproof cover- Child Elbow - XS	CEP85-XS	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
16	Bloccs waterproof cover- Child Full Arm - L	CFA73-L	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
17	Bloccs waterproof cover- Child Full Arm - M	CFA73-M	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
18	Bloccs waterproof cover- Child Full Arm - S	CFA73-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
19	Bloccs waterproof cover- Child Full Arm - XS	CFA73-XS	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
20	Bloccs waterproof cover- Child Full Leg - L	CFL77-L	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
21	Bloccs waterproof cover- Child Full Leg - M	CFL77-M	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
22	Bloccs waterproof cover- Child Full Leg - S	CFL77-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
23	Bloccs waterproof cover- Child Short Arm - L	CSA71-L	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
24	Bloccs waterproof cover- Child Short Arm - M	CSA71-M	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
25	Bloccs waterproof cover- Child Short Arm - S	CSA71-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
26	Bloccs waterproof cover- Child Short Leg - L	CSL75-L	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
27	Bloccs waterproof cover- Child Short Leg - M	CSL75-M	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	
28	Bloccs waterproof cover- Child Short Leg - S	CSL75-S	Waterproof cast and dressing cover	External use only	Class 1	Rule 4 of Annex VIII	506029574BLO5212M	

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