

Waterproof Protection for Casts & Dressings www.bloccs.com

Unit J, Lawrence Drive Stover Trading Estate Yate, Bristol BS37 5PG

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 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



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Annex - List of Devices Covered by the Declaration of Conformity

Bioccs Waterproof cover-Adult Waterproof dressing cover External use only Rule 4 of Annex VIII S060295748L05212M 2 Bioccs Waterproof cover-Adult AEP86-S dressing cover Class 1 Rule 4 of Annex VIII S060295748L05212M 3 Bioccs Waterproof cover-Adult External use only Rule 4 of Annex VIII S060295748L05212M 4 Bioccs Waterproof cover-Adult External use only Rule 4 of Annex VIII S060295748L05212M 5 Bioccs Waterproof cover-Adult Full AEP86-L dressing cover Class 1 4 Waterproof cover-Adult Full AFA72 dressing cover Class 1 S060295748L05212M 5 Waterproof cover-Adult Full AFA72 dressing cover Class 1 S060295748L05212M 6 Bioccs AFA72 dressing cover Class 1 S060295748L05212M 7 Bioccs AFA72 dressing cover Class 1 S060295748L05212M 7 Bioccs AFB7-L dressing cover Class 1 S060295748L05212M	#	Commercial name/ Trade name	Model/ Reorder/ Catalogue	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/EMDN code
Elbow - SAEP86-Sdressing coverClass 12BloccsWaterproof cover- AdultRule 4 of AFP86-MS06029574BL05212M3BloccsWaterproof cover- AdultClass 1Rule 4 of AFP86-MS06029574BL05212M4BloccsWaterproof cover- AdultKateral use onlyRule 4 of Annex VIIIS06029574BL05212M4BloccsWaterproof cover- Adult FullAEP86-LExternal use onlyRule 4 of Annex VIIIS06029574BL05212M5BloccsWaterproof cover- Adult FullAEP86-LExternal use onlyRule 4 of Annex VIIIS06029574BL05212M5BloccsWaterproof cover- Adult FullWaterproof cast and cast and cast and dressing coverClass 1S06029574BL05212M6BloccsWaterproof cover- Adult FullWaterproof cast and dressing coverClass 1Rule 4 of Annex VIII6Waterproof cover- Adult knee - LAKP87-LWaterproof cast and dressing coverClass 1Rule 4 of Annex VIII7BloccsWaterproof cover- Adult knee - SAKP87-Mdressing coverClass 1Rule 4 of Annex VIII8BloccsWaterproof cast and knee - SAKP87-Mdressing coverClass 1S06029574BL05212M9Waterproof cover- Adult knee - SAKP87-Mdressing coverClass 1S06029574BL05212M9Waterproof cover- Adult knee - SAKP87-Mdressing coverClass 1S06029574BL0521	1	waterproof	no.#	•				506029574BLO5212M	
2 waterproof cover- Aduit Elbow-M Waterproof cast and dressing cover only cast and class 1 Annex VIII Annex VIII 3 Bloccs waterproof cover- Aduit Elbow-L AEP86-M dressing cover dressing cover External use only Rule 4 of Annex VIII S06029574BL05212M 4 Bloccs waterproof cover- Aduit Full Elbow-L AEP86-L dressing cover External use only Rule 4 of Annex VIII S06029574BL05212M 5 Bloccs waterproof cover- Aduit Full Leg AFA72 dressing cover Class 1 Rule 4 of Annex VIII S06029574BL05212M 6 waterproof cover- Aduit Leg AFL76 dressing cover Class 1 Rule 4 of Annex VIII S06029574BL05212M 7 Bloccs waterproof cover- Aduit Knee - L AKP87-L dressing cover External use only Rule 4 of Annex VIII S06029574BL05212M 8 Bloccs waterproof cover- Aduit Knee - S AKP87-M dressing cover Class 1 Rule 4 of Annex VIII S06029574BL05212M 9 Waterproof cover- Aduit Knee - S AKP87-M dressing cover Class 1 S06029574BL05212M 9 Bloccs Waterproo			AEP86-S			Class 1			
Blocs Rule 4 of Annex VIII S06029574BL05212M 4 Blocs AEP86-L dressing cover Class 1 Annex VIII S06029574BL05212M 4 Blocs waterproof cover-Adult Full Waterproof cast and dressing cover External use only Rule 4 of Annex VIII S06029574BL05212M 5 Waterproof cover-Adult Full AFA72 dressing cover Class 1 S06029574BL05212M 5 Waterproof cover-Adult Full AFA72 dressing cover Class 1 S06029574BL05212M 6 Waterproof cover-Adult AFL76 Waterproof cast and dressing cover Class 1 Rule 4 of Annex VIII S06029574BL05212M 6 Blocs Waterproof cover-Adult Kape - L AKP87-L dressing cover 7 Waterproof cover-Adult AKP87-M dressing cover Class 1 S06029574BL05212M 8 Blocs Waterproof cover-Adult Knee - M AKP87-M dressing cover Class 1 S06029574BL05212M 9 waterproof cover-Adult Knee - M AKP87-S dressing cover Class 1 <td< td=""><td>2</td><td>waterproof cover- Adult</td><td>AEP86-M</td><td>cast and</td><td></td><td>Class 1</td><td></td><td>506029574BLO5212M</td><td></td></td<>	2	waterproof cover- Adult	AEP86-M	cast and		Class 1		506029574BLO5212M	
Bioccs waterproof cover-Adult Full Eg External use only Rule 4 of Annex VIII S06029574BL05212M 5 Bioccs waterproof cover-Adult Full Leg AFA72 Waterproof cast and dressing cover Class 1 Rule 4 of Annex VIII S06029574BL05212M 6 Bioccs waterproof cover-Adult Full Leg AFL76 Waterproof cast and dressing cover External use only Rule 4 of Annex VIII S06029574BL05212M 6 Bioccs waterproof cover-Adult Knee - L AFL76 Waterproof cast and dressing cover External use only Rule 4 of Annex VIII S06029574BL05212M 7 Bioccs waterproof cover-Adult Knee - M AKP87-L External use only Rule 4 of Annex VIII S06029574BL05212M 8 Bioccs waterproof cover-Adult Knee - S AKP87-M External use only Rule 4 of Annex VIII S06029574BL05212M 9 Bioccs waterproof cover-Adult Knee - S AKP87-S Waterproof cast and dressing cover Class 1 Rule 4 of Annex VIII S06029574BL05212M 10 Bioccs waterproof cover-Adult Short Leg AKP87-XL Waterproof cast and dressing cover External use only Rule 4 of Annex VIII S06029574BL05212M 11	3	waterproof cover- Adult	AE086-1	Waterproof cast and				506029574BLO5212M	
SBloccs waterproof cover-Adult Full LegAFL76External use only cast and dressing coverRule 4 of Annex VIII506029574BL05212M6Bloccs waterproof cover-Adult Knee - LAFL76External use only cast and dressing coverExternal use onlyRule 4 of Annex VIII506029574BL05212M7Bloccs waterproof cover-Adult Knee - MAKP87-Ldressing coverClass 1S06029574BL05212M8Bloccs waterproof cover-Adult Knee - SWaterproof cast and dressing coverExternal use onlyRule 4 of Annex VIIIS06029574BL05212M9Bloccs waterproof cover-Adult Knee - SAKP87-Mdressing coverClass 1S06029574BL05212M9Bloccs waterproof cover-Adult Knee - XLAKP87-SLExternal use dressing coverRule 4 of Annex VIIIS06029574BL05212M9Bloccs waterproof cover-Adult Knee - XLAKP87-SLExternal use dressing coverRule 4 of Annex VIIIS06029574BL05212M10Knee - XL waterproof cover-Adult Knee - XLAKP87-XLExternal use dressing coverRule 4 of Annex VIIIS06029574BL05212M11Bloccs waterproof cover-Adult Short Arm Short Arm AsA70Waterproof cast and dressing coverExternal use onlyRule 4 of Annex VIIIS06029574BL05212M12Bloccs waterproof cover-Adult Short LegASL74Gressing cover dressing coverExternal use onlyRule 4 of Annex VIIIS06029574BL0521	4	Bloccs waterproof cover- Adult Full		Waterproof cast and				506029574BLO5212M	
6Bloccs waterproof cover-AdultWaterproof cast and dressing coverExternal use onlyRule 4 of Annex VIII506029574BL05212M7Bloccs waterproof cover-Adult Knee - MAKP87-Ldressing coverClass 1Rule 4 of Annex VIII506029574BL05212M8Bloccs waterproof cover-Adult Knee - SAKP87-Mdressing coverClass 1Rule 4 of Annex VIII506029574BL05212M8Bloccs waterproof cover-Adult Knee - SAKP87-Mdressing coverClass 1Rule 4 of Annex VIII506029574BL05212M9Bloccs waterproof cover-Adult Knee - SAKP87-Sdressing coverClass 1Rule 4 of Annex VIII506029574BL05212M9Bloccs waterproof cover-Adult Knee - SLAKP87-SLdressing coverClass 1Rule 4 of Annex VIII506029574BL05212M10Bloccs waterproof cover-Adult Short Arm Short ArmAKP87-XLdressing coverClass 1Rule 4 of Annex VIII506029574BL05212M11Bloccs waterproof cover-Adult Short Arm Short LegASL74dressing coverClass 1Rule 4 of Annex VIII506029574BL05212M12Bloccs waterproof cover-Adult Short LegASL74dressing coverExternal use onlyRule 4 of Annex VIII506029574BL05212M12Bloccs waterproof cover-Adult Short LegASL74dressing cover dressing coverClass 1Rule 4 of Annex VIII506029574BL05212M12Bloccs waterproo	5	Bloccs waterproof cover- Adult Full		Waterproof cast and				506029574BLO5212M	
Bloccs waterproof cover-Adult Knee - MWaterproof cast and dressing coverExternal use onlyRule 4 of 	6	Bloccs waterproof cover- Adult		Waterproof cast and				506029574BLO5212M	
Bloccs waterproof cover- Adult Knee - SAKP87-SWaterproof cast and dressing coverExternal use onlyRule 4 of Annex VIII506029574BL05212M9Bloccs waterproof cover- Adult 	7	Bloccs waterproof cover- Adult		Waterproof cast and				506029574BLO5212M	
Bloccs waterproof cover-Adult Knee - XLAKP87-XLWaterproof cast and dressing coverExternal use onlyRule 4 of 	8	Bloccs waterproof cover- Adult		Waterproof cast and				506029574BLO5212M	
Bloccs waterproof cover- Adult Short ArmWaterproof cast and dressing coverExternal use onlyRule 4 of 	9	waterproof cover- Adult	AKP87-XL	Waterproof cast and				506029574BLO5212M	
Bloccs waterproof cover- Adult Short LegWaterproof 	10	Bloccs waterproof cover- Adult		Waterproof cast and				506029574BLO5212M	
12 Bloccs waterproof cover- Child Elbow - L Waterproof cast and dressing cover External use only Rule 4 of Annex VIII 506029574BL05212M 12 Bloccs CEP85-L dressing cover Class 1 Class 1	11	Bloccs waterproof cover- Adult		Waterproof cast and				506029574BLO5212M	
Bloccs External use Rule 4 of 506029574BL05212M	12	Bloccs waterproof cover- Child		Waterproof cast and				506029574BLO5212M	
13 waterproof cover- Child Waterproof cast and only Annex VIII Elbow - M CEP85-M dressing cover Class 1	13	waterproof cover- Child		Waterproof cast and	External use only		Rule 4 of Annex VIII	506029574BLO5212M	



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	Bloccs			External use		Rule 4 of	506029574BLO5212M	
14	waterproof		Waterproof	only		Annex VIII		
	cover- Child		cast and					
	Elbow - S	CEP85-S	dressing cover	ļ	Class 1			
	Bloccs			External use		Rule 4 of	506029574BL05212M	
15	waterproof		Waterproof	only		Annex VIII		
10	cover- Child		cast and					
	Elbow - XS	CEP85-XS	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BLO5212M	
16	waterproof		Waterproof	only		Annex VIII		
10	cover- Child Full		cast and					
	Arm - L	CFA73-L	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BLO5212M	
17	waterproof		Waterproof	only		Annex VIII		
17	cover- Child Full		cast and					
	Arm - M	CFA73-M	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BL05212M	
18	waterproof		Waterproof	only		Annex VIII		
10	cover- Child Full		cast and					
	Arm - S	CFA73-S	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BLO5212M	
19	waterproof		Waterproof	only		Annex VIII		
13	cover- Child Full		cast and					
	Arm - XS	CFA73-XS	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BL05212M	
20	waterproof		Waterproof	only		Annex VIII		
20	cover- Child Full		cast and					
	Leg - L	CFL77-L	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BL05212M	
24	waterproof		Waterproof	only		Annex VIII		
21	cover- Child Full		cast and					
	Leg -M	CFL77-M	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BL05212M	
22	waterproof		Waterproof	only		Annex VIII		
22	cover- Child Full		cast and					
	Leg - S	CFL77-S	dressing cover		Class 1			
	Bloccs		_	External use		Rule 4 of	506029574BL05212M	
	waterproof		Waterproof	only		Annex VIII		
23	cover- Child		cast and					
	Short Arm - L	CSA71-L	dressing cover		Class 1			
	Bloccs		_	External use		Rule 4 of	506029574BL05212M	
~	waterproof		Waterproof	only		Annex VIII		
24	cover- Child		cast and					
	Short Arm - M	CSA71-M	dressing cover		Class 1			
	Bloccs		-	External use		Rule 4 of	506029574BL05212M	
	waterproof		Waterproof	only		Annex VIII		
25	cover- Child		cast and	· ·				
	Short Arm - S	CSA71-S	dressing cover		Class 1			
	Bloccs		<u> </u>	External use		Rule 4 of	506029574BL05212M	
	waterproof		Waterproof	only		Annex VIII		
26	cover- Child		cast and	· ·				
	Short Leg - L	CSL75-L	dressing cover		Clas 1			
	Bloccs		Ŭ Ŭ	External use		Rule 4 of	506029574BL05212M	
	waterproof		Waterproof	only		Annex VIII		
27	cover- Child		cast and	/				
	Short Leg - M	CSL75-M	dressing cover		Class 1			
	Bloccs			External use		Rule 4 of	506029574BLO5212M	
28	waterproof		Waterproof	only		Annex VIII		
	cover- Child		cast and	Citry				
							1	
	Short Leg - S	CSL75-S	dressing cover		Class 1			

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