

UK Declaration of Conformity (DoC) to: Medical Devices Regulations 2002 (SI 2002 No 618, as amended)

This declaration of conformity is issued under the sole responsibility of the Legal Manufacturer. The Legal Manufacturer declares that the product(s) listed below and detailed in the attached Product Schedule meet the provisions of UK SI 2002 No 618, as amended.

Legal Manufacturer:	APA Parafricta Ltd 30 Upper High Street, Thame, Oxfordshire, OX9 3EZ Email – info@parafricta.com	
Manufacturing Site(s):	UAB Tectrix Raudondvario pl. 93, LT-47184 Kaunas, Lithuania	
Device Description/Family:	Parafricta® Bootee (see attached Product Schedule)	
UK Product Classification:	Class I, Annex IX, Rule 1 (MDD 93/42/EC)	
Conformity Route:	Annex VII (MDD 93/42/EC)	
GMDN:	59075 <i>Pressure-management sock - A non-sterile tubular device typically worn on the feet of a diabetic, rheumatoid, or insensitive-foot patient intended to reduce pressure on the skin over bony prominences to reduce the risk of developing decubitus ulcers (bedsores), and/or to reduce friction, abrasion, shear forces, and callus formation through specific design features (e.g., fabric layers impregnated with gel at the sole and that wick moisture away from the skin). The device is normally available [non-prescription] over the counter (OTC) for daily use in the home or healthcare facility. This is a reusable device.</i>	
First placed on the market:	See attached Product Schedule	
Technical Documentation Reference:	Technical Documentation - Parafricta Fabric Products 237	
Other Applicable Directives:	None	
Applied Common Standards	EN ISO 14971:2019 EN ISO 20342-1:2019 ISO 10993-1:2018 EN ISO 15223-1:2020 EN ISO 20417:2021	EN 62366-1:2015 +A1:2020 OEKO-TEX® Standard 100 BS 3424-10:1987 EN ISO 6330:2012

Signed on behalf of
APA Parafricta Ltd:

Trevor Jones
Trevor Jones (Feb 17, 2022 16:53 GMT)

Date: 17 June 2021

Trevor Jones (Chief Executive Officer)



Product Schedule

Parafriкта® Bootees

Part Number	Description	UDI-DI (GTIN)	Market Entry Date
PFFB-001XS	Parafriкта® Bootee (VELCRO® brand closure) – single	05060162890104	Feb 2007
PFFB-001S	Parafriкта® Bootee (VELCRO® brand closure) – single	05060162890111	
PFFB-001M	Parafriкта® Bootee (VELCRO® brand closure) – single	05060162890128	
PFFB-001L	Parafriкта® Bootee (VELCRO® brand closure) – single	05060162890135	
PFFB-001XL	Parafriкта® Bootee (VELCRO® brand closure) – single	05060162890142	
2xPFFB-001XS	Parafriкта® Bootee (VELCRO® brand closure) – pair	05060162890975	
2xPFFB-001S	Parafriкта® Bootee (VELCRO® brand closure) – pair	05060162890982	
2xPFFB-001M	Parafriкта® Bootee (VELCRO® brand closure) – pair	05060162890999	
2xPFFB-001L	Parafriкта® Bootee (VELCRO® brand closure) – pair	05060162891002	
2xPFFB-001XL	Parafriкта® Bootee (VELCRO® brand closure) – pair	05060162891019	
PFFB-002XS	Parafriкта® Bootee (Slip On) – single	05060162890166	Mar 2009
PFFB-002S	Parafriкта® Bootee (Slip On) – single	05060162890173	
PFFB-002M	Parafriкта® Bootee (Slip On) – single	05060162890180	
PFFB-002L	Parafriкта® Bootee (Slip On) – single	05060162890197	
PFFB-002XL	Parafriкта® Bootee (Slip On) – single	05060162890203	
2xPFFB-002XS	Parafriкта® Bootee (Slip On) – pair	05060162890920	
2xPFFB-002S	Parafriкта® Bootee (Slip On) – pair	05060162890937	
2xPFFB-002M	Parafriкта® Bootee (Slip On) – pair	05060162890944	
2xPFFB-002L	Parafriкта® Bootee (Slip On) – pair	05060162890951	
2xPFFB-002XL	Parafriкта® Bootee (Slip On) – pair	05060162890968	
PFFB-004XS	Parafriкта® Bootee (Easy on - SPU) – pair	05060162890913	Feb 2017
PFFB-004S	Parafriкта® Bootee (Easy on - SPU) – pair	05060162890906	
PFFB-004M	Parafriкта® Bootee (Easy on - SPU) – pair	05060162890890	
PFFB-004L	Parafriкта® Bootee (Easy on - SPU) – pair	05060162890883	
PFFB-004XL	Parafriкта® Bootee (Easy on - SPU) – pair	05060162890876	

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Final Audit Report

2022-02-17

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