

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® Undergarment (see attached Product Schedule)	
EC Product Classification:	Class I, Annex IX, Rule 1 (MDD 93/42/EC)	
Conformity Route:	Annex VII (MDD 93/42/EC)	
GMDN:	60525 <i>Skin treatment lower body garment - A non-sterile piece of clothing (e.g., leggings, shorts) intended to be worn around the waist, hips and legs of a person affected by a skin disorder (e.g., eczema) to protect the skin typically after treatment with a medication (e.g., ointment, cream). It is typically made of non-allergenic natural materials or a composite (e.g., viscose/nylon/elastane), and intended for 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

Parafricta® Undergarments

Part Number	Description	UDI-DI (GTIN)	Market Entry Date
PFFUG-001XS	Parafricta® Undergarment (VELCRO® brand closure)	05060162890227	Mar 2007
PFFUG-001S	Parafricta® Undergarment (VELCRO® brand closure)	05060162890234	
PFFUG-001M	Parafricta® Undergarment (VELCRO® brand closure)	05060162890241	
PFFUG-001L	Parafricta® Undergarment (VELCRO® brand closure)	05060162890258	
PFFUG-001XL	Parafricta® Undergarment (VELCRO® brand closure)	05060162890265	
PFFUG-002XS	Parafricta® Undergarment (Slip On – Brief Style)	05060162890289	Mar 2009
PFFUG-002S	Parafricta® Undergarment (Slip On – Brief Style)	05060162890296	
PFFUG-002M	Parafricta® Undergarment (Slip On – Brief Style)	05060162890302	
PFFUG-002L	Parafricta® Undergarment (Slip On – Brief Style)	05060162890319	
PFFUG-002XL	Parafricta® Undergarment (Slip On – Brief Style)	05060162890326	
PFFUG-003XS	Parafricta® Undergarment (Slip On – Boxer Style)	05060162890340	
PFFUG-003S	Parafricta® Undergarment (Slip On – Boxer Style)	05060162890357	
PFFUG-003M	Parafricta® Undergarment (Slip On – Boxer Style)	05060162890364	
PFFUG-003L	Parafricta® Undergarment (Slip On – Boxer Style)	05060162890371	
PFFUG-003XL	Parafricta® Undergarment (Slip On – Boxer Style)	05060162890388	
PFFUG-003XXL	Parafricta® Undergarment (Slip On – Boxer Style)	05060162890395	

UK Declaration of Conformity - Parafricta Undergarments V1 _17062021_signed

Final Audit Report

2022-02-17

Created:	2022-02-17
By:	Nick Garner (nick.garner@parafricta.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAAhstsqcyYGbalm3ugglJ9tlknt-HO0N2

"UK Declaration of Conformity - Parafricta Undergarments V1 _17062021_signed" History

-  Document created by Nick Garner (nick.garner@parafricta.com)
2022-02-17 - 4:05:04 PM GMT- IP address: 88.202.251.43
-  Document emailed to Trevor Jones (trevor.jones@parafricta.com) for signature
2022-02-17 - 4:05:19 PM GMT
-  Email viewed by Trevor Jones (trevor.jones@parafricta.com)
2022-02-17 - 4:06:10 PM GMT- IP address: 104.28.89.23
-  Document e-signed by Trevor Jones (trevor.jones@parafricta.com)
Signature Date: 2022-02-17 - 4:53:42 PM GMT - Time Source: server- IP address: 88.98.92.233
-  Agreement completed.
2022-02-17 - 4:53:42 PM GMT