

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 Textrix Raudondvario pl. 93, LT-47184 Kaunas, Lithuania	
Device Description/Family:	Parafricta® Bedding (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:	<p>37165 <i>Patient transfer turning sheet - a manual device used by healthcare professionals to assist in the physical movement and transfer of a person/patient (e.g., a hospitalized, a person with a disability, or a geriatric) from one position to another. The device typically has no lifting capabilities and utilizes sliding/rolling techniques to move the person. It is typically designed to turn the person from one side to another whilst he/she is lying in bed; a practice done in order to prevent bedsores and improve blood circulation.</i></p> <p>47453 <i>Basic pillowcase, reusable - A protective envelope for a pillow typically made of a thin textile material that creates a physical barrier to soiling and cross-contamination. It does not include antimicrobial or dust mite barrier/prevention properties. The device is laundered for cleaning, usually at regular intervals. This is a reusable device.</i></p> <p>47455 <i>Basic bed sheet, reusable - a large piece of fabric material intended to cover the mattress of a bed to protect it from being soiled and to provide the bed's occupant with clean, non-irritating contact surfaces (over and under); it does not include antimicrobial or nonadherent properties. It is typically made of a thin-textile or reinforced-paper material and is laundered for cleaning between periods of use. This is a reusable device.</i></p>	
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

Product Schedule

Parafricta® Bedding

Part Number	Description	UDI-DI (GTIN)	GMDN	Market Entry Date
PFFPC-001	Parafricta® Pillowcase	05060162890005	47453	Aug 2006
PFFPC-001B	Parafricta® Pillowcase (blue)	05060162891057	47453	Aug 2006
PFFSS-001	Parafricta® Single-fitted Bedsheet	05060162890012	47455	May 2007
PFFSS-001B	Parafricta® Single-fitted Bedsheet (blue)	05060162891026	47455	May 2007
PFFSS-002	Parafricta® Single Flat Bedsheet (for dynamic mattresses)	05060162890791	47455	Mar 2009
PFFSS-002B	Parafricta® Single Flat Bedsheet (for dynamic mattresses) - blue	05060162891033	47455	Mar 2009
PFFSS-003	Parafricta® Single Flat Bedsheet	05060162890814	47455	Jun 2016
PFFSS-003B	Parafricta® Single Flat Bedsheet (blue)	05060162891040	47455	Jun 2016
PFFMAS-001	Parafricta® Single Semi-fitted (Mobility Assist) Bedsheet	05060162890029	37165	Mar 2009
PFFMAS-001B	Parafricta® Single Semi-fitted (Mobility Assist) Bedsheet (blue)	05060162891149	37165	Mar 2009
PFFDS-001	Parafricta® Double Flat Bedsheet (Dual Purpose)	05060162890777	37165	Apr 2013

Signed on behalf of
APA Parafricta Ltd:

Trevor Jones
[Trevor Jones \(Feb 17, 2022 16:54 GMT\)](#)

Date: 17 June 2021

Trevor Jones (Chief Executive Officer)

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Final Audit Report

2022-02-17

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