Declaration of Conformity

Patient Care Range

EC Declaration of Conformity
European Communities Council Regulation EU 2017/746
Concerning IVD Medical Devices

Manufacturer:

APACOR LIMITED
Unit 5, Sapphire Centre
Fishponds Road
Wokingham
Berkshire RG41 2QL
United Kingdom

EC Authorised Representative :

Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

SRN: **DE-AR-000005430**

We hereby declare that the following mentioned products meet the provisions of the Council Regulation EU 2017/746 covering medical devices. All documentation is controlled and retained on company premises. This declaration of conformity is issued under the sole responsibility of Apacor Limited.

Product: See list enclosed

Classification: **Class A RULE 5 (C)**

GMDN : **63816**

Standards Applied:

Document Reference	Description
BS EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
BS EN ISO 18113-2:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labelling) - Part 2: In Vitro Diagnostic Reagents for Professional Use
ISO 13485:2016	Medical device – Quality management system – Requirements for regulatory purposes
BS EN ISO 15223-1:2021	Medical Devices -- Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied -- Part 1: General Requirements
BS EN ISO 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
BS EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
MEDDEV 2.12-1 rev. 8,2013	Guidelines on a medical devices vigilance system

Notified Body N/a

Date of Issue: **10 May 2022**

Approved By:

Sajana Vattikuti

QA/RA Manager

Apacor Ltd

Change Control History

Version	Change Description	Reason for change	Signed
01	First Issue of Document	Requirement of EN ISO 13485:2016 and IVDR EU 2017/746	

Product Description	Product Code	Pack Size
Patient Care Packs		
3.3ml SAF & Triton X Patient Care Pack	108960	30
3.3ml AlcorFix™ Pack Patient Care Pack	108962	30
3.3ml Formalin & Triton X Patient Care Pack	108980	30
3.3ml AlcorFix Stool Collection Pack	148990	30
8ml AlcorFix™ Patient Care Pack + Empty Tube	149965	30
8ml AlcorFix™ Patient Care Pack	149980	30
8ml AlcorFix™ Patient Care Single Vial	149995	15
8ml SAF & Triton X Stool Collection Pack	153000	30