Declaration of Conformity

Parasep® Range (unfilled- without chemical)

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: **GB-MF-000025569 (Manufacturer)**

SRN: **DE-AR-000005430 (EU Authorised Representative)**

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**

UDI: **Refer to the product list enclosed.**

Intended Purpose: *Parasep Faecal Concentration Kit is a closed system for a clean and efficient concentration of intestinal parasites from human faecal probes. The simple 4 step kit provides a fast and simple method to concentrate helminth ova as well as protozoan cysts/oocysts. For professional in vitro diagnostic use only.*

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
BS EN ISO 13485:2016+A11:2021	Medical device – Quality management system – Requirements for regulatory purposes

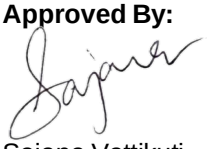
BS EN ISO 15223-1:2021	Medical Devices -- Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied -- Part 1: General Requirements
BS EN ISO 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
BS EN ISO 23640:2015	In vitro diagnostic medical devices — 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: **26 Oct 2022**

Place of Issue: **Wokingham, United Kingdom.**

Approved By:



Sajana Vattikuti

QA/RA Manager

Apacor Ltd

Change Control History

Version	Reason for change	Date
04	Addition of Accessory product ref:1457	26 Oct 2022
03	Addition of Manufacturers SRN and assigning of Basic UDI against each of the products	01 Jul 2022
02	Addition of UDI, Intended Use and Place of Issue	25 May 2022
01	Requirement of EN ISO 13485:2016 and IVDR EU 2017/746	10 May 2022

Product List

Product Description	Product Code	Pack Size	UDI
Mini Parasep® SF (15ml Solvent Free Intestinal Parasite Concentrators)			
No Additive	108000	1000	50601707710800085
No Additive	108800	50	5060170771088009D
No Additive	181000	50	5060170771810009C
Mini Parasep® - 15ml Intestinal Parasite Concentrators:			
No Additive	146001	1000	50601707714600195
No Additive	146000	50	50601707714600093
Midi Parasep® SF - 50ml Solvent Free Intestinal Parasite Concentrators:			
No Additive	149900	50	506017077149900B5
No Additive	180050	50	5060170771800509L
Midi Parasep® - 50ml Intestinal Parasite Concentrators:			
No Additive	145000	50	5060170771450008U
Midi Parasep® - 50ml Intestinal Parasite Concentrators:			
No Additive	909000	50	506017077909000BL
Accessories			
Mini Parasep® Cap	1543	40	5060170771543SW
Mini Parasep® Filter & Sedimentation Tube	1559	30	5060170771559TD
Midi Parasep® Cap	1456	40	5060170771456T2
Midi Parasep® Cap & Spoon	1457	100	5060170771457T4