



# Declaration of Conformity

Parasep<sup>®</sup> Product Group (filled -with Chemical)

		Doc No.	TD002
Declaration of Conformity		Version. No.	06
		Issue Date	06 <sup>th</sup> Jul 2023
Prepared By	Sajana Vattikuti	Pages	1 of 5
Approved By	Janet Mackenzie		



**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/ocysts. For professional in vitro diagnostic use only.*

*The kits are available as reagent ready.*

**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

Declaration of Conformity		Doc No.	TD002
		Version. No.	06
Prepared By	Sajana Vattikuti	Issue Date	06 <sup>th</sup> Jul 2023
Approved By	Janet Mackenzie	Pages	2 of 5

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:** 06<sup>th</sup> Jul 2023

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

**Approved By:**



QA/RA Manager  
Apacor Ltd

## Change Control History

Version	Reason for change	Date
06	Change from UDI to Basic UDI-DI as per Annex IV of the IVDR Regulation	06 Jul 2023
05	Addition of new products (916000, 916001,916002)	07 Apr 2023
04	Addition of new product codes	31 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

Declaration of Conformity		Doc No.	TD002
		Version. No.	06
Prepared By	Sajana Vattikuti	Issue Date	06 <sup>th</sup> Jul 2023
Approved By	Janet Mackenzie	Pages	3 of 5

Product Description	Product Code	Pack Size	Basic UDI-DI
<b>Mini Parasep® SF</b>			
Mini Parasep® SF 3.3ml Apafix™	108801	40	5060170771088019F
Mini Parasep® SF 3.3ml Alcorfix™	108810	40	5060170771088109G
Mini Parasep® SF 3.3ml Formalin & Triton X	108900	40	5060170771089009J
Mini Parasep® SF 3.3ml SAF & Triton X	108920	40	5060170771089209Q
Mini Parasep® SF 3.3ml MIF & Triton X	108935	40	506017077108935A5
Mini Parasep® SF 3.3ml Bailenger + 40ml Triton X	181010	40	5060170771810109F
Mini Parasep® SF 3.3ml MIF + 40ml Triton X	181020	40	5060170771810209J
Mini Parasep® SF 3.3ml SafEFix™ Fixateur Eco	181030	40	5060170771810309M
Mini Parasep® SF 3.3ml SafEFix™ Colour	181035	40	5060170771810359X
Mini Parasep® SF 2.4ml SafEFix™ Fixateur Eco	902500S	40	506017077902500S7J
Mini Parasep® SF 3.3ml Apafix™	108801LCD-B	40	506017077108801LCD-BNX
Mini Parasep® SF 3.3ml SafEFix™ Colour	181035LCD-B	40	506017077181035LCD-BPM
Mini Parasep® SF 8ml SafEFix™ Colour	180085LCD-B	40	506017077180085LCD-BRK
<b>Mini Parasep®</b>			
Mini Parasep® 2.4ml Apafix™	146003	40	50601707714600399
Mini Parasep® 2.4ml Apafix™ + 40ml Ethyl Acetate	146004	40	5060170771460049B
Mini Parasep® 2.4ml Formalin	146200	40	5060170771462009D
Mini Parasep® 2.4ml Formalin & Triton X	146300	40	5060170771463009J
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Ethyl Acetate	146400	40	5060170771464009P
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Empty Bottle	146400.MI	40	506017077146400.MI4X
Mini Parasep® 2.4ml SAF & Triton X	146500	40	5060170771465009U
Mini Parasep® 2.4ml SAF & Triton X + 40ml Ethyl Acetate	146501	40	5060170771465019W
Mini Parasep® 2.4ml Apafix™	146005	520	5060170771460059D
<b>Mini Parasep® (Including Spoons)</b>			
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Ethyl Acetate	900000	40	5060170779000009M
Mini Parasep® 2.4ml SAF & Triton X + 40ml Ethyl Acetate	901000	40	5060170779010009U
Mini Parasep® 2.4ml Apafix™	902500	40	506017077902500AU
Mini Parasep® Stain Kit	903000	40	506017077903000AA
<b>Midi Parasep® SF</b>			
Midi Parasep® SF 8ml Apafix™	149901	40	506017077149901B7
Midi Parasep® SF 8ml Formalin & Triton X	149910	40	506017077149910B8
Midi Parasep® SF 8ml Alcorfix™	249300	40	506017077249300AL
Midi Parasep® SF 8ml Bailenger + 40ml Triton X	180060	40	5060170771800609P
Midi Parasep® SF 8ml MIF + 40ml Triton X	180070	40	5060170771800709S
Midi Parasep® SF 8ml SafEFix™ Ecological Fixative	180080	40	5060170771800809V
Midi Parasep® SF 8ml SafEFix™ Colour	180085	40	506017077180085A7
Midi Parasep® SF 8ml SAF & Triton X	149920	40	506017077149920BB
Midi Parasep® SF -Filters & Sedimentation tubes only	916001	40	506017077916001BC
<b>Midi Parasep®</b>			
Midi Parasep® 6ml Apafix™	145002	40	5060170771450028Y
Midi Parasep® 6ml Apafix™ + 80ml Ethyl Acetate	145003	40	50601707714500392
Midi Parasep® 6ml Formalin	145200	40	50601707714520096
Midi Parasep® 6ml Formalin & Triton X	145300	40	5060170771453009B
Midi Parasep® 6ml Formalin & Triton X + 80ml Ethyl Acetate	145400	40	5060170771454009G
Midi Parasep® 6ml SAF & Triton X	145500	40	5060170771455009M

Declaration of Conformity		Doc No.	TD002
		Version. No.	06
Prepared By		Issue Date	06 <sup>th</sup> Jul 2023
Approved By		Pages	4 of 5
Sajana Vattikuti			
Janet Mackenzie			

Product Description	Product Code	Pack Size	Basic UDI-DI
Midi Parasep® 6ml SAF & Triton X + 80ml Ethyl Acetate	145501	40	5060170771455019P
Midi Parasep® 6ml Apafix	145005	180	50601707714500596
<b>Midi Parasep® (Including Spoons)</b>			
Midi Parasep® 6ml Formalin & Triton X + 80ml Ethyl Acetate	905000	40	506017077905000AQ
Midi Parasep® 6ml SAF & Triton X + 80ml Ethyl Acetate	906000	40	506017077906000AX
Midi Parasep® 6ml Apafix™	907500	40	506017077907500BX
<b>Midi Parasep® SF (Including Spoons)</b>			
Midi Parasep SF 8ml SAF & Triton X	916000	40	506017077916000BA
Midi Parasep SF 8ml SAF & Triton X – Mixing tubes +Caps	916002	40	506017077916002BE
<b>Accessories</b>			
Triton X-100 Solution	1472	50ml	5060170771472SY
Ethyl Acetate	1473	250ml	5060170771473T2
1:10 Triton X	172018	250ml	5060170771720189T
Triton X Solution	1499	500ml	5060170771499TL

Declaration of Conformity		Doc No.	TD002
		Version. No.	06
Prepared By Sajana Vattikuti		Issue Date	06 <sup>th</sup> Jul 2023
		Pages	5 of 5
Approved By Janet Mackenzie			

# Atitikties deklaracija

Parasep<sup>®</sup> produktų grupė (užpildyta cheminėmis medžiagomis)

Atitikties deklaracija		Dok. nr.	TD002
		Versijos nr.	06
		Leidimo data	2023-07-06
Paruošė	Sajana Vattikuti	Lapai	1 iš 5
Patvirtino	Janet Mackenzie		

EB atitikties deklaracija  
Europos Bendrijų Tarybos reglamentas  
ES 2017/746 dėl IVD medicinos prietaisų

**Gamintojas:** APACOR LIMITED  
Unit 5, Sapphire Centre Fishponds  
Road Wokingham  
Berkshire RG41 2QL  
Jungtinė Karalystė

**Įgaliotas atstovas EB:** Medical Device Safety Service GmbH (MDSS)  
Schiffgraben 41  
30175 Hannover  
Vokietija

**SRN:** GB-MF-000025569 (gamintojas)

**SRN:** DE-AR-000005430 (įgaliotas atstovas ES)

Pareiškiame, kad toliau išvardyti gaminiai atitinka Tarybos reglamento ES 2017/746 dėl medicinos prietaisų nuostatas. Visa dokumentacija yra kontroliuojama ir išlieka kompanijos žinioje. Už šią atitikties deklaraciją išimtinai atsako Apacor Limited.

**Produktas:** Žr. pridedamą sąrašą.

**Klasifikacija:** A klasė, 5 taisyklė (C)

**GMDN:** 63816

**UDI:** Žr. pridedamą gaminių sąrašą

**Numatytoji paskirtis:** *Parasep išmatų koncentravimo rinkinys yra uždara sistema, skirta švariai ir veiksmingai koncentruoti žarnyno parazitus iš žmogaus išmatų mėginių. Paprastas 4 žingsnių rinkinys suteikia greitą ir paprastą metodą helmintų kiaušialąstėms bei pirmuonių cistoms ir (arba) oocistoms koncentruoti. Skirtas tik profesionaliam in vitro diagnostikos naudojimui.*

*Rinkinius galima įsigyti kaip paruoštus reagentus.*

**Taikomi standartai:**

Dokumento nuoroda	Aprašymas
BS EN ISO 14971:2019	Medicinos prietaisai. Rizikos valdymo taikymas medicinos prietaisams.
BS EN ISO 18113-2:2011	<i>In vitro</i> diagnostikos medicinos prietaisai. Gamintojo pateikiama informacija (ženklinimas) - 2 dalis. <i>In vitro</i> diagnostikos reagentai profesionaliam naudojimui.
BS EN ISO 13485:2016+A11:2021	Medicinos prietaisai. Kokybės valdymo sistema. Reglamentavimo reikalavimai.

		Dok. nr.	TD002
		Versijos nr.	06
		Leidimo data	2023-07-06
Paruošė	Sajana Vattikuti	Lapai	2 iš 5
Patvirtino	Janet Mackenzie		

BS EN ISO 15223-1:2021	Medicinos prietaisai. Simboliai, naudojami medicinos prietaisų etiketėse, ženkliniame ir pateiktinoje informacijoje. 1 dalis: bendrieji reikalavimai.
BS EN ISO 13612:2002	<i>In vitro</i> diagnostikos medicinos prietaisų veiksmingumo vertinimas.
BS EN ISO 23640:2015	<i>In vitro</i> diagnostikos medicinos prietaisai. <i>In vitro</i> diagnostikos reagentų stabilumo vertinimas.
MEDDEV 2.12-1 rev. 8,2013	Medicinos prietaisų budros sistemos gairės.

**Notifikuotoji įstaiga:** Netaikoma.

**Leidimo data:** 2023-07-06

**Leidimo vieta:** Wokingham, Jungtinė Karalystė.

**Patvirtinta:**

/parašas/ /spaudas/

Kokybės užtikrinimo ir reglamentavimo vadybininkas (QA/RA)

Apacor Ltd.

**Pakeitimų istorija**

Versija	Pakeitimo priežastis	Data
06	Perėjimas nuo UDI prie pagrindinio UDI-DI pagal IVDR reglamento IV priedą.	2023-07-06
05	Naujų produktų įtraukimas (916000, 916001, 916002)	2023-04-07
04	Naujų produktų kodų įtraukimas	2022-10-31
03	Gamintojų SRN įtraukimas ir bazinio UDI priskyrimas kiekvienam produktui	2022-07-01
02	UDI, numatytojo naudojimo ir leidimo vietos įtraukimas	2022-05-25
01	EN ISO 13485:2016 ir IVDR ES 2017/746 reikalavimai	2022-05-10

Atitikties deklaracija		Dok. nr.	TD002
		Versijos nr.	06
Paruošė	Sajana Vattikuti	Leidimo data	2023-07-06
Patvirtino	Janet Mackenzie	Lapai	3 iš 5

Produkto aprašymas	Produkto kodas	Pakuotės dydis	Bazinis UDI-DI
<b>Mini Parasep® SF</b>			
Mini Parasep® SF 3.3ml Apafix™	108801	40	5060170771088019F
Mini Parasep® SF 3.3ml Alcorfix™	108810	40	5060170771088109G
Mini Parasep® SF 3.3ml Formalin & Triton X	108900	40	5060170771089009J
Mini Parasep® SF 3.3ml SAF & Triton X	108920	40	5060170771089209Q
Mini Parasep® SF 3.3ml MIF & Triton X	108935	40	506017077108935A5
Mini Parasep® SF 3.3ml Bailenger + 40ml Triton X	181010	40	5060170771810109F
Mini Parasep® SF 3.3ml MIF + 40ml Triton X	181020	40	5060170771810209J
Mini Parasep® SF 3.3ml SafEFix™ Fixateur Eco	181030	40	5060170771810309M
Mini Parasep® SF 3.3ml SafEFix™ Colour	181035	40	5060170771810359X
Mini Parasep® SF 2.4ml SafEFix™ Fixateur Eco	902500S	40	506017077902500S7J
Mini Parasep® SF 3.3ml Apafix™	108801LCD-B	40	506017077108801LCD-BNX
Mini Parasep® SF 3.3ml SafEFix™ Colour	181035LCD-B	40	506017077181035LCD-BPM
Mini Parasep® SF 8ml SafEFix™ Colour	180085LCD-B	40	506017077180085LCD-BRK
<b>Mini Parasep®</b>			
Mini Parasep® 2.4ml Apafix™	146003	40	50601707714600399
Mini Parasep® 2.4ml Apafix™ + 40ml Ethyl Acetate	146004	40	5060170771460049B
Mini Parasep® 2.4ml Formalin	146200	40	5060170771462009D
Mini Parasep® 2.4ml Formalin & Triton X	146300	40	5060170771463009J
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Ethyl Acetate	146400	40	5060170771464009P
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Empty Bottle	146400.MI	40	506017077146400.MI4X
Mini Parasep® 2.4ml SAF & Triton X	146500	40	5060170771465009U
Mini Parasep® 2.4ml SAF & Triton X + 40ml Ethyl Acetate	146501	40	5060170771465019W
Mini Parasep® 2.4ml Apafix™	146005	520	5060170771460059D
<b>Mini Parasep® (su šaukšteliais)</b>			
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Ethyl Acetate	900000	40	5060170779000009M
Mini Parasep® 2.4ml SAF & Triton X + 40ml Ethyl Acetate	901000	40	5060170779010009U
Mini Parasep® 2.4ml Apafix™	902500	40	506017077902500AU
Mini Parasep® Stain Kit	903000	40	506017077903000AA
<b>Midi Parasep® SF</b>			
Midi Parasep® SF 8ml Apafix™	149901	40	506017077149901B7
Midi Parasep® SF 8ml Formalin & Triton X	149910	40	506017077149910B8
Midi Parasep® SF 8ml Alcorfix™	249300	40	506017077249300AL
Midi Parasep® SF 8ml Bailenger + 40ml Triton X	180060	40	5060170771800609P
Midi Parasep® SF 8ml MIF + 40ml Triton X	180070	40	5060170771800709S
Midi Parasep® SF 8ml SafEFix™ Ecological Fixative	180080	40	5060170771800809V
Midi Parasep® SF 8ml SafEFix™ Colour	180085	40	506017077180085A7
Midi Parasep® SF 8ml SAF & Triton X	149920	40	506017077149920BB
Midi Parasep® SF -Filters & Sedimentation tubes only	916001	40	506017077916001BC
<b>Midi Parasep®</b>			
Midi Parasep® 6ml Apafix™	145002	40	5060170771450028Y
Midi Parasep® 6ml Apafix™ + 80ml Ethyl Acetate	145003	40	50601707714500392
Midi Parasep® 6ml Formalin	145200	40	50601707714520096
Midi Parasep® 6ml Formalin & Triton X	145300	40	5060170771453009B
Midi Parasep® 6ml Formalin & Triton X + 80ml Ethyl Acetate	145400	40	5060170771454009G
Midi Parasep® 6ml SAF & Triton X	145500	40	5060170771455009M

Atitikties deklaracija		Dok. nr.	TD002
		Versijos nr.	06
		Leidimo data	2023-07-06
Paruošė	Sajana Vattikuti	Lapai	4 iš 5
Patvirtino	Janet Mackenzie		

Produkto aprašymas	Produkto kodas	Pakuotės dydis	Bazinis UDI-DI
Midi Parasep® 6ml SAF & Triton X + 80ml Ethyl Acetate	145501	40	5060170771455019P
Midi Parasep® 6ml Apafix	145005	180	50601707714500596
<b>Midi Parasep® (su šaukšteliais)</b>			
Midi Parasep® 6ml Formalin & Triton X + 80ml Ethyl Acetate	905000	40	506017077905000AQ
Midi Parasep® 6ml SAF & Triton X + 80ml Ethyl Acetate	906000	40	506017077906000AX
Midi Parasep® 6ml Apafix™	907500	40	506017077907500BX
<b>Midi Parasep® SF (su šaukšteliais)</b>			
Midi Parasep SF 8ml SAF & Triton X	916000	40	506017077916000BA
Midi Parasep SF 8ml SAF & Triton X – Mixing tubes +Caps	916002	40	506017077916002BE
<b>Priedai</b>			
Triton X-100 Solution	1472	50ml	5060170771472SY
Ethyl Acetate	1473	250ml	5060170771473T2
1:10 Triton X	172018	250ml	5060170771720189T
Triton X Solution	1499	500ml	5060170771499TL



Atitikties deklaracija		Dok. nr.	TD002
		Versijos nr.	06
		Leidimo data	2023-07-06
Paruošė	Sajana Vattikuti	Lapai	5 iš 5
Patvirtino	Janet Mackenzie		