

EUROPEAN UNION

DECLARATION OF CONFORMITY

Manufacturer:

Reingenuity Ltd
Brentwood Units, Lincoln Road,
Faldingworth, Market Rasen
Lincolnshire, LN8 3SF

SRN:

US-MF-000017554

EU Authorized Representative:

Eurolink Europe
Compliance Limited 25
Herbert Place Dublin
D02 AY86
Republic of
Ireland IE-AR-
000002852

SRN:

We the undersigned certify and declare under our sole responsibility that the following apparatus

Conforming Apparatus:

Fecal Parasite Concentrator

EMDM:

W0503010201

Basic UDI-DI:

850085309

Device Name and UDI-DI Numbers:

See Page 2

Risk Class:

A

Technical Document Reference No:

Attachment 01 – Paradevice EU
Declaration of Conformity (DoC)

Common Specifications

EN ISO 23640 2015
EN ISO 14971 2019
EN 13612 2002
EN ISO 18113-3 2024
EN ISO 15223-1 2021
EN 62366-1 2020
EN 18113-2 2024
EN 18113-1 2024

Conforms to the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL of 5 April 2017 on medical devices

Signed:



R. Reardon, Director, Reingenuity, Ltd.

Date: 6 November 2024

Issued: Dublin, Ireland

Product Line Item	Product Name	Product Reference Code	UDI-PI (GTIN)	Bar Code 128
1	Mini Paradevice 1000 PK	001-007	00850085309020	 00850085309020
2	Mini Paradevice Patient Collection 3mL Justfix 25 PK	003-007	00850085309082	 00850085309082
3	Justfix+ 15mL Transport Vial 60 PK	010-007	00850085309037	 00850085309037
4	Mini Paradevice 3mL Justfix 40 PK	100-007	00850085309174	 00850085309174
5	Paradevice Justfix Color 40 PK	107-007	00850085309228	 00850085309228
6	Midi Paradevice 8mL Justfix 40 PK	110-007	00850085309235	 00850085309235
7	Mini Paradevice Justfix Color 40 PK	117-007	00850085309068	 00850085309068
8	Mini Paradevice 50 PK	700-007	00850085309143	 00850085309143
9	Justfix+ 15mL (3x Vials) Spanish + Portuguese 20 PK	707-007	00850085309129	 00850085309129
10	Midi Paradevice 50 PK	710-007	00850085309150	 00850085309150
11	Culture+ 15mL Transport Vial 60 PK	717-007	00850085309099	 00850085309099