ELITech MICROBIO
Parc d'activités du plateau – Allée d'Athènes
83870 Signes - France
Tél : +33 (0)4 94 88 55 00
www.elitechgroup.com

EU DECLARATION OF CONFORMITY

(According to Annex IV of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices)

Manufacturer's Name: ELITech MICROBIO **SRN :** FR-MF-000025235

Manufacturer's Address: Parc d'activités du plateau – Allée d'Athènes
83870 Signes - France

Ref, Product Names & Basic UDI-DI: See Attachment

Analytes:

- ELIStain Para-Color and ELIStain Paratest are *in vitro* diagnostic devices intended for use by medical professionals to stain stool specimens, as a step of standard laboratory practice in diagnosing parasitic diseases.
- ELIStain Paratest also allows the concentration of the stools before staining.
- MYCOPLASMA Stabilizer reagent does not allow the detection and/or measurement of an analyte. MYCOPLASMA Stabilizer increases the preservation time of mycoplasmas after freezing at -20°C in mycoplasma transport medium
- UMMt *RevolutioN* medium allows the transport and preservation of *Ureaplasma urealyticum / Ureaplasma parvum* and *Mycoplasma hominis* from various clinical samples
- UMMt AMIES *RevolutioN* medium (2.6 mL) allows the transport and storage of Ureaplasma urealyticum / Ureaplasma parvum (U.u.) and Mycoplasma hominis (M.h.) from AMIES transport medium (Σ-TRANSWAB® or ESwab®) or universal transport medium for viruses, chlamydia, mycoplasma, and ureaplasma (Σ-VCM™) seeded with various clinical samples.

Device Classification: Class A
Conformity Assessment Procedure: Annex I and II

We, ELITech MICROBIO, herewith declare that the EU declaration of conformity is issued under the sole responsibility of the manufacturer. The above-mentioned products are in conformity with following Regulation and Standards:

Regulation Applied: REGULATION (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79 EC

Standards applied: EN ISO 13485:2016, EN ISO 13612:2002, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 18113-1:2022, EN ISO 18113-2:2022, EN ISO 23640:2015, IEC 62366-1:2015

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And therefore, bear the CE Marking. CE

Place, Date of First Issue of DoC : in Signes, on 18-05-2022

Names: Laurent DAELS, Managing Director ; Axelle DOCTRINAL, Regulatory Affairs Engineer

Signatures : Date : 05-01-2026

Signé par : Laurent Daels B8BBCD6FB05D422...

Signé par : Axelle Doctrinal 63424899FF53463...

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Attachment:

Ref Number	Product Name	EMDN	Basic UDI-DI
66702	ELIStain Paratest	W0104050199	3661540PARstain01HZ
66704	ELIStain Para-Color	W0104050102	3661540PARstain01HZ
00064	MYCOPLASMA Stabilizer	W0104010899	3661540UROstabi01WN
00061	UMMt *RevolutioN*	W0104010203	3661540UROscree02VP
00083	UMMt AMIES *RevolutioN*	W0104010203	3661540UROscree03VR