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 : ELI.H.A Echinococcus and HYDATIDOSE are *in vitro* diagnostic devices intended to allow the semi quantitative determination of anti-*echinococcus granulosus* serum antibodies by indirect haemagglutination

Device Classification: Class B

Conformity Assessment Procedure: Annex IX chapter 1 and 3

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

And therefore, bear the CE Marking.

Notified Body : Name **:** GMED (Groupement pour l'évaluation des dispositifs médicaux)
Number : 0459
Address: 1, rue Gaston Boissier - 75015 Paris - France
EU Certificate of Conformity : 39618 rev. 1
Issue Date : 29/10/2025
Expiry Date : 06/03/2029

Place, Date of First Issue of DoC : in Signes, on 05-01-2025

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

Date: 05/01/2026

Signatures:

Signé par : Laurent Daels B8BBCD6FB05D422...

Signé par : Axelle Doctrinal 63424899FF53463...

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Attachment:

Ref Number	Product Name	EMDN	Basic UDI-DI
66604	ELI.H.A Echinococcus	W0105050204	3661540PARhemag027E
524800	Hydatidose	W0105050204	3661540PARhemag027E