EC Declaration of Conformity

IVD

In accordance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

Manufacturer Information

Manufacturer:

LOMINA Superbio a.s.
Na Radosti 184/59, Prague 5, 158 00, Czech Republic
ID: CZ07420099, www.lomina.ch, SÚKL reg.: 061583

Medical Device (Product) Identification Data.

Name: Lomina Toxoplasmosis IgG/IgM Test

REF La-TOXO-Pro

Intended use:

The Lomina Toxoplasmosis IgG/IgM Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM anti-Toxoplasma Gondii (T. gondii) and IgG anti-T. gondii in human whole blood, serum or plasma. This kit is intended to be used as a screening test and as an aid in the diagnosis of infection with T. gondii. Any reactive specimen with the Lomina Toxoplasmosis IgG/IgM Test must be confirmed with alternative testing method(s) and clinical findings.

Version for Health Care Professionals

Category of in vitro diagnostic medical device: IVD OTHER

The manufacturer declares that the properties of the above in vitro diagnostic medical device fulfil all the requirements laid down in Directive 98/79/EC, and that the in vitro diagnostic medical device will perform in accordance with its intended purpose. The manufacturer further declares that he has taken measures to ensure compliance of the medical device placed on the market with the essential requirements and the manufacturer's technical documentation pursuant to Annex III of Directive 98/79/EC.

Harmonized standards:
EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, EN 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 23640:2015

Name: Michal Horáček, PMP, MBA
Position: CEO
Valid from: 2022/05/05

Michal Horáček

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