EC Declaration of Conformity

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

MANUFACTURER INFORMATION:

LOMINA SUPERBIO a.s.
Bucharova 2657/12, Praha 5, 158 00, Česká Republika
ID: CZ07420099, www.lomina.ch, +420 722 633 203

PRODUCT NAME:

FLUORESCENCE IMMUNOASSAY CHROMATOGRAPHY ANALYSER

REF LSLC-20

INTENDED USE:

The LSLF-20 analyser is intended for sensitive result reading and interpretation of LOMINA IVD assays working on a principle of sensitive detection of nano-fluorescent spheresduring immuno-chromatographic reaction. Analyser is tobe used with POC test strips and reagents manufactured by LOMINA Superbio a.s..

Edition for medical professionals according to Annex III

CATEGORY OF IN VITRO DIAGNOSTIC MEDICAL DEVICE:

IVD Other

The manufacturer declares that the properties of the above in vitro diagnostic medical device (IVDD) 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 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, (IEC 61010--1:2017, IEC 61010-2-081:2019, IEC 61010-2-101:2018, IEC 61326-1:2012, IEC 61326-2--6:2012, IEC 62304:2006+A1:2015,) EN 62366-1:2015+AC:2015.

Signature:
Name: Michal HORACEK MBA PMP
Position: General manager
Issued as of: 29. SEPTEMBER 2020
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CE IVD

Czech State Institute for Drug Control registration number # 061583