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 CEA Test

REF La-CEA-Pro

Intended use:

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The Lomina CEA Test is a rapid chromatographic immunoassay for the qualitative detection of CEA in whole blood, serum or plasma to aid in monitoring of cancer patients.

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

Digitálně podepsal Michal Horáček
Datum: 2022.05.25 11:23:37 +02'00'

Signature:

v. La-CEA-Pro_001