

# 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 Male Fertility Test

**REF** La-SPERM-Pro

**Intended use:**

The Lomina Male Fertility Test is a rapid chromatographic immunoassay for in vitro qualitative detection of Acrosomal Protein SP-10 found on sperms to estimate of sperm concentration in human semen above or below 15 million / mL. Sperm concentration can be used for assistant diagnosis and curative effect observation of male infertility, and provide guidance for reproductive planning of the eligible couples.

## **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

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Position: CEO  
Valid from: 2022/05/05

Signature:

