

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 COC Test

REF La-D-COC-Pro

Intended use:

The Lomina COC Test is a rapid chromatographic immunoassay for the qualitative detection of Cocaine metabolite, Benzoylcegonine, in human urine at a cut-off concentration of 300 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

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: Aleš Mrkáček
Position: CEO
Valid from: 2022/05/05

Signature:

