

EC-Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex III

Product Number: 101036
Product Name: nal von minden Drug-Screen® Alcohol Test
Classification: Other Products
Manufacturer: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers, Germany

We herewith declare on our sole responsibility that all batches of the above In-vitro-diagnostic device are conform with the Essential Requirements Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The product is suitable for the intended application (only professional users). Relevant standards and guidelines are applied.

The conformity assessment procedure for this product was carried out before 26 May 2022 in accordance with Directive 98/79/EC. Due to the previously established validity period of 24 months for each Declaration of Conformity issued by us, this is an updated version of the Declaration of Conformity issued prior to 26 May 2022. It is now valid until the end of the transitional period for this legacy product. Since 26 May 2022, no significant changes have been made to the design and intended use of the product in accordance with the requirements for legacy products.

This document is valid until 2027-05-26

Moers, 2023-08-22

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