EC-Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex IV (excluding sections 4 and 6)

Product Name/ Description	Article Numbers (REF)
NADAL® PSA Test	602003

Classification: Annex II, List B
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 listed in-vitro-diagnostic devices are conform to 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 products are suitable for the intended application.
Relevant standards and guidelines are applied.

The Conformity assessment procedure is performed in accordance with Annex IV, exclusive 4 and 6, of directive 98/79/EC – Full Quality Assurance System

Notified Body:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg, Germany
Identification Number:	0197

The conformity assessment procedure for this product was carried out before 26 May 2022. This is an updated version of the Declaration of Conformity issued prior to 26 May 2022, which has now been issued until the expiration date of the nal von minden EC- Certificate with registration number HL 1034230-1 (Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Full Quality Assurance System, Annex IV, excluding sections 4 and 6), namely 2025-05-26. 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 devices.

Moers, 2022-12-20

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