

## » Declaration of clearance «

Under the MDR (Medical Device Regulation, EU Regulation 2017/745), materials used for the production of medical products must be provided, amongst others, with a *declaration of clearance* with respect to their toxicological properties.

✓ **nora**<sup>®</sup> products are free of constituents posing toxicological and carcinogenic risks as set down under EU Regulation 2017/745.

The closed-cellular surface structure of **nora**<sup>®</sup> materials also minimises the risk of harm to health in the form of germ and bacterial colonies and facilitates complete hygienic cleaning and disinfection.

Owing to their properties, **nora**<sup>®</sup> materials are suitable for the processing of Class 1 medical products.

**nora**<sup>®</sup> products undergo regular testing at renowned testing institutes and are certified to bear the following quality labels:

- *dermatological seal* of the Dermatest institute
- *SG tested for harmful substances* of the testing and research institute PFI Pirmasens

These requirements are fulfilled as a result of continuous production monitoring by an extensive *quality management system*. The ISO 9001:2015 certification safeguards unvarying quality in the manufacture, sales, and marketing of **nora**<sup>®</sup> products. This is supplemented with an *environmental management system* complying with ISO 14001:2015.

Confirmed in January 2023. Valid from 01/01/2023 to 31/12/2024.



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