

SG plus Certification:

Your PLUS in terms of

**quality, hygiene
and safety**

**in orthopaedic shoe manufacturing,
orthopaedic engineering and
rehabilitation applications**

nora[®]



The exclusive SG plus Seal of Approval

Since the introduction of the Medical Products Act (MPG), medical products have been subject to stringent statutory stipulations with regard to toxicology and carcinogenicity.

Products used by orthopaedic shoe engineers and orthopaedic technicians to make medical products must conform to these statutory requirements. The SG Seal of Approval is based on significantly more stringent criteria than the statutory stipulations of the MPG.

The **SG plus Seal of Approval** enhances and develops the requirements of the long-standing SG seal to include microbial and physical testing as well as inspection of our production facilities.

SG plus certification means: Unequivocal safety as defined by the Medical Products Act.

Qualität · Hygiene



nora[®]

Zertifizierte und
überwachte
Produktionsstätte



Extension of the eco-label 'Schadstoffgeprüft (SG)' by:

Your asset of quality:

Tested wear behaviour and stability of **nora**[®] products through dynamic long-term stress tests.

Your asset of hygiene:

Proven disinfectability of contaminated foot beddings and inserts made of **nora**[®] materials.

Your asset of safety:

Apart from the materials, the production sites as well as the production processes of **nora**[®] products in Weinheim are regularly examined and certified.

» Conformity declaration «

For materials used to produce a medical product, the German Medical Products Law (MPG – Directive 93/42/EEC) requires the certification of safety of the materials used with regard to

- toxicology and
- carcinogenity.

nora[®] products fully comply with the requirements of MPG. **nora**[®] products do not contain any toxicologically harmful and no carcinogenic substances as e.g. carcinogenic amines from azo dyes.

In addition, **nora**[®] products are certified by regular tests carried out by renowned test institutes and may bear the following quality seals:

- **skin tolerability certificate of the Institute Fresenius**
- **SG test mark "Schadstoffgeprüft"**
- **SG plus test mark**

A prerequisite for the use of the above mentioned quality seals is a continuous production monitoring by a quality management system. The certification according to DIN EN ISO 9001 guarantees the constant quality of manufacture, distribution, and marketing of the **nora**[®] products.

Confirmed in December 2007.

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Medical Products Act (MPG)



In accordance with the stipulations of the Medical Product Act (MPG), materials used for manufacturing medical products must be toxicologically and carcinogenically safe.

This means the materials may neither trigger allergic reactions of the skin nor have carcinogenic effects.

nora® products meet these statutory requirements in full. This is confirmed by the declaration of conformity.

The Fresenius skin compatibility report



Since 1988, skin compatibility for skin-coloured **nora**® products has been confirmed by the Fresenius Institute in regular and comprehensive tests and studies.

These products bear the Fresenius seal of approval "Geprüfte Hautverträglichkeit" ("Tested quality compatible with the skin").

SG Seal of Approval



This seal of approval, confirming freedom from pollutants, is issued by various approved testing institutes after intensive material analysis.

Besides verifying the parameters stipulated by law, the SG seal also confirms, for example, that no carcinogenic amines have been detected. Numerous **nora**® products have been tested since 1998 against the SG pollutant test criteria listing.

The decisive difference

The seal of approval, confirming freedom from pollutants, is issued by various approved testing institutes after intensive analysis of the materials. Based on the latest findings, this seal of approval verifies that there is no risk to the health of dealers, processing firms and patients. The SG Seal of Approval rules out the use of carcinogenic or cancer-causing substances.

The certificate entitles the testing institute to take random samples from the ongoing production process. A further prerequisite is a fully functioning and effective quality assurance system (e.g. DIN EN ISO 9001). **nora systems GmbH** invariably has all its **nora**® products certified!

The test report (Prüfbericht) does not entitle the product to bear the SG Seal of Approval.

The test report can only serve as a "snapshot", i.e. it only concerns itself with the testing of a material sample.



Pay attention to the difference between a test report and a certificate (Zertifikat)! Only a certificate entitles the product to bear the SG Seal of Approval.

Your plus in quality: tested resilience and stability



Testing "pressure test"

How much stress will each product stand up to? This question was the focal point of the PFI's investigations into the permanent dynamic stress of the materials. These tests are designed to examine the stress bearing characteristics of **nora**® materials. PFI's verdict:

All **nora**® products excel in terms of very good rebound resilience.

In pressure tests, a broad bandwidth of deformability was determined, depending on the Shore A hardness. These results provide orthopaedic technicians and orthopaedic shoe engineers with valuable insights for the purpose of putting together various materials to suit specific applications.

To provide processing firms with a more convenient overview, the relevant **nora**® products are divided into bedding (e.g. **Lunairmed**), permanently resilient (e.g. **Lunalastik**) and stabilising (e.g. **Lunasoft AL**) materials.

The material was stressed around 100,000 times with the equivalent of 60 kg with its thickness measured and compared before and after the stress routine.

More detailed information is available from nora systems GmbH

(e-mail: info-shoe@nora.com).



Your plus in hygiene: disinfectability

Besides the „Geprüfte Hautverträglichkeit“ (“tested skin compatibility”) certification, **nora®** Luna products offer a further important advantage: the disinfection of contaminated foot bedding and insole materials with commercially available disinfectants.

In particular, the rising numbers of diabetic patients with open wounds (ulcers) render necessary a simple yet effective method of destroying bacteria. Furthermore, any infestation of skin and nail fungi also demands effective remedies.

Essentially, effective disinfection can be achieved only with closed-cell materials. In contrast to closed-cell **nora®** products, bacteria and fungi get into open-cell foam materials and can no longer be got rid of.



Testing “Mould cultures”

Following comprehensive testing conducted by the PFI laboratory, the disinfectability was verified in a series of microbiological tests involving precisely defined bacteria and fungi.

The physical properties of the **nora®** Luna products are not impaired by the disinfectant. A product may bear the “tested disinfectability” seal of approval only if it achieves a germ reduction rate of 100 %.

Detailed **care instructions** are available free of charge from nora systems GmbH (e-mail: info-shoe@nora.com)



Your plus in safety: certified production

Lasting safety concerning medical products means more than simply testing the materials involved. It also means having the **production facilities and the production process inspected by the PFI.**



Each and every step in the manufacturing chain is checked and documented against the criteria specified in the quality management system conforming to DIN ISO 9001, following actual implementation in the ongoing production process.

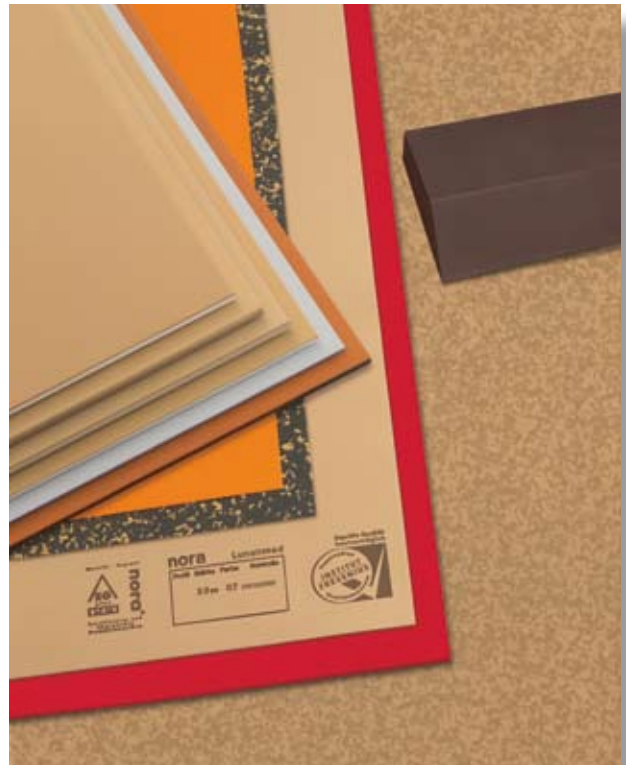


Batch labelling to facility tracking

This process testing routine includes: Selection of raw materials, incoming goods inspection, mixture monitoring, production checks, final inspection and testing all the way through to packaging checks and identification tracking options.

The SG plus seal of approval is awarded only when all factors have been validated and all tests passed.

Summing up: The Weinheim production site for nora® sheets and the quality control provided by the nora systems GmbH company guarantee a consistently high level of quality.



Your additional plus: future-oriented environmental compatibility

All **nora**® products are free of toxic heavy metals and carcinogenic aromatic amines from colouring agents and dyes. Moreover, **nora**® products do not contain PCPs, CFCs and carcinogenic N-nitrosamines.

As one of the first manufacturers in this type of industry, our company has been registered in the list of companies complying with the EC Eco-Audit Ordinance under the registration number D-153-00016.

In 2000, our company was also granted the certification conforming to DIN EN ISO 14001 (environmental management systems).



EMAS
GEPRÜFTES
UMWELTMANAGEMENT

Register-No.:
D-153-00016



Certified
DIN EN ISO 14001

The sum of your advantages

SG plus certification means: Unequivocal safety as defined by the Medical Products Act. Besides the disregard for materials that can trigger allergic reactions or have carcinogenic effects, a plus in terms of quality, hygiene and safety means tested disinfectability with commercially available disinfectants, outstanding quality regarding permanent static and dynamic stress and certified production. The SG plus Seal of Approval is awarded only when all factors have been validated and all tests passed.

Qualität · Hygiene



nora®

Zertifizierte und
überwachte
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