# Certificate

## Quality Management System

**ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH**, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.

Through an audit performed on behalf of

**THEO Manufacturing BV**
**Sleperweg 44, 6222 NK Maastricht, The Netherlands**

it could be demonstrated that a quality management system

according to **DIN EN ISO 13485:2016**
"Medical devices – Quality management systems – Requirements for regulatory purposes"

for **design, manufacturing and distribution of wound care products**

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report mentioned hereafter.

Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

| Report number | Registered under | Valid until |
|---|---|---|
| **168-22-0504** | **Z/22/04829E** | **6 May 2025** |

Valid as of: 19 May 2022

Certification body

ID no. 0045