# Certificate

#### mdc medical device certification GmbH

certifies that

## **NICOLAY**

GREAT PERFORMANCE ENGINEERING

Nicolay GmbH Graf-Zeppelin-Straße 21 72202 Nagold Germany

for the scope

development, production and distribution of cables and connector systems for medical technology as well as sensors, interfaces, assemblies and components for devices for monitoring vital parameters

with the location and the scope

Nicolay Romania Srl Str. Insulei 1 540337 Tirgu Mures, Romania

production of cables and sensors for medical technology

has introduced and applies a

## **Quality Management System**

The mdc audit has proven that this quality management system meets all requirements of the following standard

### **EN ISO 13485**

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from<br/>Valid until2022-08-17Registration no.D1084300013Report no.P21-01791-244903Berlin2022-08-12

Head of Certification Body





Internet: http://www.mdc-ce.de