Certificate

mdc medical device certification GmbH

certifies that

Creative Balloons GmbH Bruchsaler Straße 22 68753 Waghäusel **Germany**

for the scope

development, manufacture and distribution of non-sterile incontinence products and balloon components for medical devices

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:2016 - ISO 13485:2016

Valid from 2020-12-14 Valid until 2023-12-13 Registration no. D1479400001 Report no. P20-01838-190686

Stuttgart 2020-12-14

Head of Certification Body





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