Certificate

mdc medical device certification GmbH

certifies that

Healthy.io Ltd. 2 Ibn Gabirol St. Tel Aviv, 6407702 Israel

for the scope

Design, development, manufacture and distribution of in-vitro diagnostic devices and medical devices with smartphone and tablet applications for urine testing and wound management

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
Valid until2021-05-03
2024-05-02Registration no.D1417700013Report no.P20-01871-191141Stuttgart2021-04-26

Head of Certification Body





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