Certificate

mdc medical device certification GmbH

certifies that



Healthy.io Ltd. 8 Yitzhak Sadeh St. Tel Aviv, 6777508 Israel

with the locations listed in the attachment

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 2022-08-15
Valid until 2024-05-02
Registration no. D1417700019
Report no. P22-00426-243029
Stuttgart 2022-08-15

Head of Certification Body





Attachment of the certificate

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Location	Scope
Healthy.io Ltd. 8 Yitzhak Sadeh St. Tel Aviv, 6777508 Israel	Design, development, manufacture and distribution of in-vitro diagnostic devices and medical devices with smartphone and tablet applications for urine testing and wound management
Healthy.io Ltd. 3 Ha-Sadna St. Holon, 5881402 Israel	Manufacture and distribution of in-vitro diagnostic devices and medical devices for urine testing and wound management (production site)



Head of Certification Body