

Certificate

We hereby certify the company

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



with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in 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

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2024-11-03
Valid until 2027-05-02

Registration No. D1417700022
Report No. P23-01448-310039

Stuttgart, 2024-10-28



Certification Body



Sites included in the certification:

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)

Stuttgart, 2024-10-28


Certification Body