EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: IL-MF-000024892)

Inspir Labs Ltd.

1st HaTahana St.
Kfar Saba, 4453001
Israel

EU Authorized Representative: MedNet EC-Rep GmbH, Borkstraße 10, 48163 Münster, Germany (DE-AR-000000002)

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-08-03	Registration No.	D1493900003
Valid until:	2028-08-02	Evaluation Report No.	P22-01633-250936

Stuttgart, 2023-08-03

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: Lumena -NIV mask

Risk class: IIa