

EU Quality Management System Certificate

We hereby certify the company

Hasharon Dental Center Ltd.
Ha-Yayin St. 4, P.O.B 580
Zihron Ya'akov, 3095006
Israel

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets 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 from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2024-11-04
Valid until 2029-11-03

Registration No. D1371200009
Report No. P23-00521-264821

Stuttgart, 2024-11-04



Notified Body



EU Authorized Representative:

Obelis S.A.
Boulevard Général Wahis 53
1030 Brüssel, Belgium
BE-AR-000000106

Devices:

Diamond-Coated Dental Burs – Sterile and Non-Sterile

Risk class: IIa

Tungsten Carbide Burs – Sterile and Non-Sterile

Risk class: IIa

Diamond Dental Discs – Non-Sterile

Risk class: IIa

Dental Polishers – Non-Sterile

Risk class: IIa
