# EU Quality Assurance Certificate

We hereby certify the company

**Carmex Precision Tools Ltd.**
**P.O. Box 404**
**Maalot 2101302**
**Israel**

the introduction and application of a quality management system in accordance with Annex XI, Part A, Section 6 of Regulation (EU) 2017/745 for manufacturing and final inspection.

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

## Annex XI – Part A (Production Quality Assurance)

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 XI, Section 7 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

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|---|---|---|---|
| Valid from | 2025-06-18 | Registration No. | D1444800007 |
| Valid until | 2030-06-17 | Report No. | P24-00794-301655 |

Stuttgart, 2025-06-18

Notified Body

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

## EU Authorized Representative:

MedNet EC-Rep GmbH
Borkstraße 10
48163 Münster
Germany
DE-AR-000000002

## Devices:

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Uncoated Implant Drills and Accessories

Risk class: IIa

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Coated Implant Drills and Accessories

Risk class: IIa

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