# EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

**SpofaDental a.s.**
**Markova 238**
**50601 Jicin**
**Czech Republic**

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 / article 22 for sterile procedure packs, of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. With an exception for sterile procedure packs, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa the surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body shall be affixed by the manufacturer to the devices.

For the placing on the market of class III devices and class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

| | |
|---|---|
| **Single Registration Number of the Manufacturer (SRN):** | CZ-MF-000000945 |
| **Actor ID Number (for sterile procedure packs only):** | N/A |
| **Authorised Representative:** | see Section 1 |
| **Limitations and Conditions:** | see Section 2 |
| **List of Products, Risk Classification and Details:** | see Section 3 |
| **Certificate History:** | see Section 4 |

| | | | |
|---|---|---|---|
| Certificate number: | 44 911 240240 | Valid from: | 2026-05-11 |
| Certification decision report No.: | 3538 8858 | Valid until: | 2031-05-10 |
| | | First issued: | 2026-05-11 |
| | | Issue date: | 2026-05-11 |
| | | Edition: | 1 |

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen, Germany
tuev-nord-cert.de
medical@tuev-nord.de

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Annex IX, Chapters I and III
Certificate number: 44 911 240240

## Section 1, Authorised Representative

| | |
|---|---|
| **Company name:** | N/A |
| **Street, No.:** | -- |
| **Postal Code, City:** | -- |
| **Country:** | -- |

## Section 2, Limitations and Conditions

| | |
|---|---|
| **The validity of this Certificate depends on:** | N/A |
| **and the following conditions:** | None |
| **and / or is limited to the following:** | N/A |

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Section 3, List of Products, Risk Classification and Details

**CLASS IIA**

| | |
|---|---|
| **Category of device (MDx Code)** | MDN 1103<br>Non-active dental implants and dental materials |
| **TD assessment report no.:** | 3540 3773 |
| **Devices or groups of devices:** | Adhesor<br>Adhesor Carbofine<br>Evicrol<br>Kavitan Cem<br>Kavitan Plus |

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Section 4, Certificate History

| Edition | Date | Action leading to revision | Certification decision report No. |
|---|---|---|---|
| 1 | 2026-05-11 | Initial certification | 3538 8858 |

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