Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 (MDR) regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	microtec, Dr. Frank Speckmann OHG Inh. Michael Nolte
Manufacturer address and contact details	Rohrstraße 14 58093 Hagen
Single Registration Number (SRN) (if available)	DE-MF-000014608

Notified body name (if applicable)	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH / DNV MEDCERT GmbH
Notified body number (if applicable)	0482
Directive Certificate number(s) to which this confirmation is made (if applicable)	1549DE417200915
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	27.05.2024
End date of extended validity/transition period	31.12.2028

Product group	Halteelemente
Risk class	IIa (MDD) / IIa (MDR)
EMDN-Code and description	Q010280: PROSTHETIC DENTISTRY DEVICES - ACCESSORIES
Products	Dentale Geschiebe Steckriegel Friktionselemente für Teleskopkronen

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above

- Directive Certificate(s) covering the listed device(s) were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

  Expired *after* 27 May 2024:

  Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

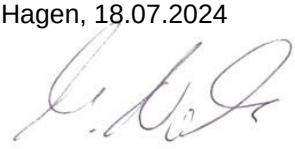
  A QMS in accordance with Article 10(9) MDR is in place.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

microtec, Dr. Frank Speckmann OHG Inh. Michael Nolte
Hagen, 18.07.2024



Michael Nolte, PRRC

microtec, Dr. Frank Speckmann OHG
Inh. Michael Nolte
Rohrstraße 14
58093 Hagen

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Halteelemente **Dentale Geschiebe** (Geschiebetechnik) **Catalogue number** — **device name** 810 — MT1 mini 45° Patrize 820 — MT2 mini 90° Patrize 830 — MT3 mini 45° Patrize 840 — MT4 normal 90° Patrize 811 — MT Gewindekappe 808 — MT Befestigungsschraube 809 — MT Aktivierschraube 812 — MT Gewindekappe 8011 — MT1 mini 45° 8012 — MT1 mini 45° 8021 — MT2 mini 90° 8022 — MT2 mini 90° 8031 — MT3 normal 45° 8032 — MT3 normal 45° 8041 — MT4 normal 90° 8042 — MT4 normal 90°	1549DE417200915	27.05.2024	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH / DNV MEDCERT GmbH 0482	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH / DNV MEDCERT GmbH 0482	31.12.2028	---
Halteelemente **Steckriegel** (Riegeltechnik) **Catalogue number** — **device name** 401 — Microlock Riegel komplett 402 — Microlock Riegelachse 403 — Microlock Riegelhülse	1549DE417200915	27.05.2024	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH / DNV MEDCERT GmbH 0482	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH / DNV MEDCERT GmbH 0482	31.12.2028	---

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Halteelemente **Friktionselemente für Teleskopkronen** (Teleskopkronentechnik) **Catalogue number** / **device name** 6010 Quick-rep Friktionselement 610 Telerep Friktionselement 131 Frisoft Friktionselement 132 Frisoft Micro-Friktionsaufnahme 710 TK1 Friktionselement 711 TK1 Schraube 720 TK1 Platzhalter 7100 TK1 komplett 7200 TK1 plus komplett 131132 Frisoft komplett FL710 TK1 Friktionselement grün	1549DE417200915	27.05.2024	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH / DNV MEDCERT GmbH 0482	MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH / DNV MEDCERT GmbH 0482	31.12.2028	---