

### MANUFACTURER'S DECLARATION

<b>Manufacturer Name:</b>	<b>Medical Instinct® Deutschland GmbH</b>
Manufacturer Address and Contact Details:	Graseweg 24, D-37120 Bovenden +49 (0) 5593-95196; info@medical-instinct.de
Single Registration No.: (SRN)	DE-MF-000006923
Notified Body Name:	DQS Medizinprodukte GmbH
Notified Body Number:	0297
Directive Certificate Number(s) to which this confirmation is made:	Certificate Registration No. 456947 MR2 EC Certificate Unique ID: 170773833
Original Expiry Date as indicated on the Directive Certificate prior to the Extension of the Validity:	2023-11-01
End Date of extended Validity/Transition Period:	2028-12-31

We declare that the Directive Certificate mentioned above is in accordance with the Regulation (EU) 2023/607. The Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards. The Products in the table below continue to comply with directive 93/42/EEC (MDD) and meet the requirements for extending the validity of the Directive Certificate in accordance with Article 120 of the regulation (EU) 2017/745 MDR.

- The devices continue to comply with the MDD
- There are no significant changes in the design and intended purpose
- The devices 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.
- A QMS in accordance with Article 10(9) MDR is in place
- Formal applications to our notified body – in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment – is submitted.
- The notified body under MDD is the same as it will be under MDR: DQS Medizinprodukte GmbH (NANDO Code 0297)

Device Family	Device	Class MDD/MDR
Dental Implant Systems	BoneTrust® Implant Systems	IIb
Prosthetic Components and Superstructures	Healing Abutments Abutments Retaining Screws	IIb
Surgical Instruments and Drills	BoneTrust® Drilling Systems BoneTrust® Instruments	IIa

Signed for and on behalf of the manufacturer:

Medical Instinct® Deutschland GmbH

Bovenden, 2023-10-19

*Jan Worlitz*  
Jan Worlitz / Geschäftsführer (PRRC)

