TOSI FOSHAN MEDICAL EQUIPMENT COMPANY LIMITED

ADD: No.405-407, 409-411, Building 3, South China International Medical Device Center, No. 17, Jichang Road, Luocun, Shishan Town, Nanhai Dist., Foshan, 528226 Guangdong, P.R. China
Tel: 0086-757-8180-9990 Website: www.tosidental.com

Manufacturer's Self-Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic 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/or*[1]
- 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	TOSI FOSHAN MEDICAL EQUIPMENT COMPANY LIMITED
Manufacturer address and contact details	No.405-407, 409-411, Building 3, South China International Medical Device Center, No. 17, Jichang Road, Luocun, Shishan Town, Nanhai Dist., Foshan, 528226 Guangdong, P.R. China
Tel :	0086-757-81809990
Name and Title of Authorized:	Yu Li Dong / General Manager
e-mail :	sales@tosidental.com

Authorised Representative name (if applicable)	Lotus NL B.V.
Authorised Representative address and contact details	Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands

Notified body name	TÜV Rheinland LGA Products GmbH
Notified body number	0197
Tel :	+49 911 655-5225
Name and Title of Authorized:	Samuel Qin / Certification body

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 23 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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e-mail :	markcheck@tuv.com
Directive - Certificate number(s)	- EC Certificate No : **DD2163315-1** (Production Quality Assurance / Annex V of the Directive 93/42/EEC on Medical Devices) **-** Notified Body Confirmation Letter **Reference:TOSIF _PLA_2024-03-04; order #10924236**
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26.05.2024
End date of extended validity/transition period	31.12.2028

We TOSI FOSHAN MEDICAL EQUIPMENT COMPANY LIMITED attest that we are in compliance with all the requirements mentioned on Regulation 2023/607 as follow:

- Our medical devices continue to comply with Medical Device Directive (MDD).
- There are no significant changes in design and intended purpose of our devices.
- The devices do not present an unacceptable risk to the health or safety of patients,users,or other persons,nor to other aspects of the protection of public health.
- There are no reports of serious incidents and field safety corrective actions identified in the post-market phase.
- TOSI FOSHAN MEDICAL EQUIPMENT COMPANY LIMITED has a quality management system compliant with MDR (EU)2017/745 article 10(9).
- An official application has been made to TÜV Rheinland LGA Products GmbH, which is a notified Body for EC Certification in accordance with Regulation 2017/745 (MDR) and identified in NANDO with the number 0197, and a written agreement has been signed on 17.05.2024.
- Our products are under the supervision and inspection of TÜV Rheinland LGA Products GmbH.

We, TOSI FOSHAN MEDICAL EQUIPMENT COMPANY LIMITED also attest that our transition from MDD to MDR is in progress.

Consequently, the Medical Device Directive (MDD) 93/42/EEC certificate DD2163315-1 expiring date 2024-05-26 are still valid till the edition of Medical Device Regulation (MDR). The new certificate and no later than 31st December 2028.
No new MDD certificate will be issued by our notified body TUV Rheinland LGA Products GmbH but only "Notified Body Confirmation Letter, Reference TOSIF _PLA_2024-03-04; order #10924236" has been issued.

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Date, Place :

June 21, 2024

No.405-407, 409-411, Building 3, South China International Medical Device Center, No. 17, Jichang Road, Luocun, Shishan Town, Nanhai Dist., Foshan, 528226 Guangdong, P.R. China

Authorized Name and Title:

Yu Li Dong / General Manager

Signature / Stamp:

Schedule of Devices

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

Device name	Risk Class	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
High-speed Air Turbine Handpieces **Model:** TX-114, TX-124, TX-164	Class IIa	N/A	**Certificate :** DD2163315-1 **NB :** 0197
Straight Handpieces **Model:** TX-414A(8)	Class IIa	N/A	**Certificate :** DD2163315-1 **NB :** 0197
Angle Handpieces **Model:** TX-414A(7)	Class IIa	N/A	**Certificate :** DD2163315-1 **NB :** 0197
Air Motors **Model:** TX-414A(9)-B2, TX-414A(9)-M4	Class IIa	N/A	**Certificate :** DD2163315-1 **NB :** 0197