Certificate of Compliance

Technical file of the company mentioned below has been observed 93/42/EEC for Medical device directive has been taken as references for the processes.

Product Requirements of the organization has been assessed in accordance with the Directive applicable of product for: **Dental, Surgical, ENT and Beauty Instruments**

Certificate Number:	TCE/UK277/03742204
Company Name:	**ZAMAHA UK LTD**
Company Address:	335 Crescent Road, Bolton, Manchester - BL3 2NA, UK
Applicable EC Directives & Annex:	93/42/EEC & Annex V / 2007/47EEC Module A AnnexVII for Class 1 Medical Devices & Essential Health and safety requirements
Applicable Harmonized Standards:	EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008+A1:2013 ISO 17664-1:2021, ISO 11197:2019, ISO 13485:2016

This certificate permits the above named organization to issue declarations of performance in support of CE Marked product with to the scope of certification as stated within this certificate; thereby confirming to interested parties the above named organization has produced the product to the agreed specification.

Initial Certification Date:	16 April 2024
Issue Date:	22 April 2024
Expiry Date:	21 April 2025
Revision:	00

CE

This Certificate is issued against the product sample conforming to the essential requirements as per the Directive. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

After preparation of necessary technical documentation as well as the EC conformity declaration the required CE marking can be affixed on the product. Other relevant directives have to be observed.

To verify the certificate please scan the above QR code.

Approved on Behalf of the Certification Board

Technical Standards Institute

Signature By Scheme Manager

Email: info@techstandi.com
Website: www.techstandi.com

This certificate remains the property of the Technical Standards Institute and may be withdrawn without notice and is valid based on the above named organization ensuring continued commitment to legal compliance against the Directive as defined and associated. TSI used to assess the performance of the declared characteristics, if not change, and the product, and the manufacturing condition in the plant are not modified significantly. The CE marked shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of conformity for all relevant Directives.