DECLARATION OF CONFORMITY

MANUFACTURER	Quantel Medical 1 Rue du Bois Joli, CS 40015 Cournon d'Auvergne, 63808 CEDEX FRANCE
SRN	FR-MF-000009724
COMPETENT AUTHORITY	ANSM
In accordance with the following Regulation:	Regulation EU 2017/745

Hereby declare that:

PRODUCT	ABSolu including probes: *LIN 50 MHz probe (BHF-50 LIN)* *20MHz-5A Annular probe (B20-5A)* *15 MHz probe (B1)* *Probeam probe (TP-02-las probe)* *Biometry probe (TP-01-b probe)* *Standardised A Probe (Std-A-8MHz probe)* *and ultrasound accessories*
BASIC UDI-DI	37005426ABSOLUAP
MDR CLASSIFICATION	IIa – MDR 2017/745, Annex VIII, Chapter 3: rule 10.
INTENDED PURPOSE	Ultrasound diagnostic imaging of the eye and orbit.

The medical device referenced above is conform with the Regulation EU 2017/745.

This declaration is based on the EU Quality Management system certificate (N°39711) according to EU Regulation 2017/745, Annex IX chapters I and III, issued by **GMED**, notified body **N°0459**.

DATE OF DECLARATION	October 16th 2024,
AUTHORISED SIGNATORY	Bruno PAGES *Quality and Regulatory Affairs Director*

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