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Amtsgericht, Göttingen;
HRB 205 464

TO WHOM IT MAY CONCERN

Datum/Date: 2024-05-21

Declaration Letter Medical Device Regulation compliance (EU transition to MDR 2017/745)

Let it be known that LISA Laser Products GmbH (LISA), located Albert-Einstein-Str. 4, 37191 Katlenburg- Lindau, Germany hereby confirms that we implemented the requirements for the transition from MDD (93/42/EEC) to the MDR (Regulation (EU) 2017/745) regulation, filed out applications with our Notified Body TÜV SÜD, and completed the required MDR updates of our Quality Management System documentation, our Dossiers, Technical files (including Declaration of Conformities), submitted the Transition self-Declaration and MDR application letters. Our Notified Body TÜV SÜD has agreed to the extension of our CE # - G1_011426_0026_Rev.00 until May 25, 2028 while completing the review of our MDR submission.

LISA is registered as an economic operator at EUDAMED (SRN DE-MF-000005036).

Currently all medical devices are placed onto the market under MDD regulation and our EC-Certificate (extended until 2028-05-26). During this period LISA Laser Products will also ensure conformity with applicable MDR Regulations.

Katlenburg-Lindau – 2024-05-21

Yours sincerely,

Carlos O. Acosta
Global Director RA/QA
Management Representative / PRRC