Declaration of Conformity

Following the European directive 93/42/EEC
For Medical Devices

Device Category:	Laser and Light Based Technology
Device Identification:	**Soprano Titanium**
GMDN Code:	58786 / 58935
Classification:	IIb Rule 9
Technical File reference:	ICE2DE-11-19
Manufacturer and E.U. Responsible:	Alma Lasers GmbH Nordostpark 100-102 90411 Nuernberg, Germany

We, the undersigned, hereby declare that the medical devices referenced above conform to the European Directive 93/42/EEC, and within these requirements we have prepared the required technical documentation, put into place corrective action and vigilance procedures.

This declaration is supported by the Full Quality Assurance System (Annex II) approval, certification number: Nº 28231, issued by GMED, notification body identification number 0459, headquartered at: 1 rue Gaston Boissier, 75015 Paris, France.

Avi Hirshnzon
EVP QA & RA

May 20, 2020
Date

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