



**Ultrasound
Solutions**

Document Commercial – Commercial Document

DC.QUAL.001

Declaration of Conformity of SDT Laser products to USA regulations

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| 02 | GEL 18 Feb 2016 | Precised url for downloading ucm094366.pdf | RBT |
| 01 | GEL 28 Apr 2015 | Original | ADG |
| Ver. | Author | Nature of modification | Verified |



Ultrasound Solutions

This Declaration is made following strictly « Laser Notice No. 50 », issued by the
U.S. Department of Health and Human Services,
Food and Drug Administration,
Center for Devices and Radiological Health,

www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm094366.pdf

**SDT International NV SA,
415 Boulevard de l'Humanité,
B-1190 Brussels,
BELGIUM**

declares under its own responsibility, that the SDT products :

| Code Article | Description |
|--------------|----------------------|
| FUR200 | SDT200 Receiver |
| FUR270 | SDT270 Receiver |
| FUR200A | SDT200 ATEX Receiver |
| FUR270A | SDT270 ATEX Receiver |

- were built in conformity with IEC/EN 60825-1:2007 (Safety of laser products - Part 1) and thus comply with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007, **and**
- comply with the applicable sections of the Code of Federal Regulations, Title 21 (21 CFR) :
 - o 1010.2 Certification
 - o 1010.3 Identification
 - o 1010.4 Variances
 - o 1040.10(a) Applicability
 - o 1040.10(c)(2) Removable laser systems
 - o 1040.10(f)(10) Manual reset mechanism
 - o 1040.10(h)(2) Purchasing and servicing information
 - o 1040.10(i) Modification of a certified product
 - o 1040.11(b) Surveying, leveling and alignment laser products
 - o 1040.11(c) Demonstration laser products

April 28, 2015, André DEGRAEVE, Managing Director