

ITALIAN REGISTRATION

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Order No.: MN 6710-2018

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Annex A - List of Devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN Code	Class	Rule
1.	LLT808- Laser	B-Cure Laser	Low Intensity Laser Device	LLLT-808 has a low level laser beam which is monochromatic of wavelength of 808nm, and is coherent. The soft-laser affects the skin's surface and simultaneously penetrates the skin without heating or hurting the skin. This soft laser treatment bio-stimulates the body's natural healing mechanisms on a cellular and systemic level. The result: every kind of cell receives the energy required for activation of its optimal functioning in the body, thus allowing it to "self-heal" and overcome specific problem specified in the intended use.	60410	IIa	9
2.	LLT808- Pro	B-Cure Laser Pro			60410		
3.	LLT808- Dental Pro	B-Cure Laser Dental Pro			60410		
4.	LLT808- Sport	B-Cure Laser Sport			60410		

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

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