

Declaration of Conformity

ILUX XP F 30

We declare that the laser device model **ILUX XP F 30**, serial number _____ complies with the essential requirements of the Annex I, Directive 93/42/CEE and subsequent amendments.

The device is a class IIb according to Annex IX of this Directive.

The device complies with the following standards:

- EN ISO 14971:2012
- EN 60601-1:2006/A1:2013
- EN 60601-2-22: 2007 (Third Edition) + A1:2012
- EN 60825-1: 2014
- EN 60601-1-2:2015
- EN 60601-1-6:2010
- EN 62366:2008
- EN 62304:2006/AC:2008
- EN ISO 15223-1:2016
- ISO 10993-1:2009/AC:2010

Compliance with the Production Quality System is certified and controlled by IMQ S.p.A. This device has been designed, manufactured and checked in compliance with Annex II esc.4 of Directive 93/42/EEC subsequently modified by Directive 2007/47/EC.

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