



EC Declaration of Conformity

Manufacturer:	COMPEX, spol. s r.o. Palackeho trida 924/105 612 00 Brno Czech Republic Company ID: 12164739
Product:	Portable DC electrocautery JETT PLASMA For Her II
Product name:	JETT PLASMA For Her II
GMDN code:	45630 – Electrocautery system, line - powered
UMDNS code:	11422 - Electrocautery Units, Line-Powered
Catalogue number:	PLASMAFORHII
Classification:	The risk class IIb, implementing rule 9 in accordance with Annex No. IX EC Directive 93/42/EEC
Demonstrate of Compliance:	Process in annex II without (4) EC Directive 93/42/EEC.
The manufacturer is exclusively responsible for the Declaration of Conformity.	
We declare, that our product meets the basic requirements, which are in Annex No. I in EC Directive 93/42/EEC. This product used as directed is safe for its purpose and the manufacturer takes measures. These measures ensure the conformity of the marketed medical device in the technical documentation of the product. Technical file is stored by manufacturer.	
Used regulations:	EN 60601-1:2006/A1:2013/A11:2011/A12:2014/AC:2014-07, EN 60601-1-2:2015, EN 60601-1-6:2010/A1:2015, EN ISO 10993-1:2009/AC:2010-06, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008+A1:2013
Notified body	Institute for testing and certification, a.s. tř. Tomáše Bati 299 763 02 Zlín NB no. 1023
ES certification:	20 0417 QS/NB
Beginning of the sign CE:	2020-09-30
Place, Date of publication:	Brno, 2020-10-01
Valid until:	2024-05-27
Statutory representative, Position:	Ing. Radek Nešpor, CEO
Signature:	 <p>COMPEX, spol. s r.o. Palackeho třída 105, 612 00 Brno IČ: 121 64 739 ----- 3-</p>