



COMPEX, spol. s r. o.

A/ Palackého třída 105, 612 00 Brno T/ +420 606 071 596 E/ info@jett.eu / WWW.JETT.EU

## EC Declaration of Conformity

<b>Manufacturer:</b>	COMPEX, spol. s r. o. Palackého třída 924/105 612 00 Brno Czech Republic Company ID: 12164739
<b>Product:</b>	Portable DC electrocautery JETT PLASMA For Her II
<b>Product name:</b>	JETT PLASMA For Her II
<b>GMDN code:</b>	45630 – Electrocautery system, line - powered
<b>UMDNS code:</b>	11422 - Electrocautery Units, Line-Powered
<b>Catalogue number:</b>	PLASMAFORHII
<b>Classification:</b>	The risk class IIb, implementing rule 9 in accordance with Annex No. IX EC Directive 93/42/EEC
<b>Demonstrate of Compliance:</b>	Process in annex II without (4) EC Directive 93/42/EEC.
<b>The manufacturer is exclusively responsible for the Declaration of Conformity.</b>	
<b>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.</b>	
<b>Used regulations:</b>	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
<b>Notified body</b>	Institute for testing and certification, a.s. tř. Tomáše Bati 299 763 02 Zlín NB no. 1023
<b>ES certification:</b>	20 0417 QS/NB
<b>Beginning of the sign CE:</b>	2020-09-30
<b>Place, Date of publication:</b>	Brno, 2020-10-01
<b>Valid until:</b>	2024-05-27
<b>Statutory representative, Position:</b>	Ing. Radek Nešpor, CEO
<b>Signature:</b>	<div>COMPEX, spol. s r. o. Palackého třída 105, 612 00 Brno IČ: 121 64 739</div> 