

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 LIFT MEDICAL
Product name:	JETT PLASMA LIFT MEDICAL
Product code:	Plasma Medic
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 EC Directive 93/42/EEC
This declaration of conformity is issued under the sole responsibility of the manufacturer.	
We declarate, 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	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany NB no. 0123
ES certification:	No. G1 003186 0002 Rev.00
Beginning of the sign CE:	2018-10-09
Place, Date of publication:	Brno, 2018-10-10
Statutory representative, Position:	Ing. Radek Nešpor, CEO
Signature:	 <p>COMPEX, spol. s r.o. Palackého třída 105, 612 00 Brno IČ: 121 64 739</p>