

EC Declaration of Conformity

Manufacturer:	CIMPAX ApS Lille Pilevang 4 3550 Slangerup Denmark	
Conformity Assessment Route:	Annex II of the Medical Device Directive 93/42/EEC as amended, Clause 3.2	
Applied standards:	ISO 13485:2016	
Notified Body:	3EC International a.s. Hraničná 18, 82105 Bratislava, Slovak Republic Notified Body No. 2265	
Certificate Numbers:	EC	No. 2020-MDD/QS-120/A
	ISO	No. M-0484/20
Medical Device:	Product Name:	CIMPAX® C-VAC TORNADO CIMPAX® ELECTRODES
	Product Type:	Electrosurgical Diathermy Pencils, Surgical Smoke Evacuation & Accessories for Electrosurgical Diathermy Pencils
	REF:	See Annex 1
	Classification:	Class IIb, rule 9

We, the manufacturer, hereby declare that the above-mentioned devices comply with the relevant provisions of Council Directive 93/42/EEC as amended concerning medical devices and its transpositions into national laws of the Member States in which the above-mentioned medical devices are distributed.

Applicable Standards	
Quality management	EN ISO 13485:2016
Risk management	EN ISO 14971:2012
Labelling and information	EN 1041:2008 EN ISO 15223-1:2016
Design	EN 62366:2008
Clinical evaluation	MEDDEV 2.7/1 Rev. 4
Medical electrical equipment	EN 60601-1:2006 EN 60601-2-2:2009
Biological evaluation	EN ISO 10993-1:2009 EN ISO 10993-5:2009 EN ISO 10993-7:2008/AC:2009 ISO 10993-10:2010 EN ISO 10993-11:2018
Sterilization and bioburden	EN 556-1:2001/AC:2006 EN ISO 11135-1:2007 EN ISO 11737-1:2006/AC:2009
Cleanroom	ISO 14644-1:2015
Sterilized packaging	EN 868-5:2009 EN ISO 11607-1:2020 EN ISO 11607-2:2020
Aging	ASTM F1980 - 16

Place and Date of issue:

Denmark, April 19th 2021

Patrick Busch-Madsen
Quality Assurance Manager

Annex 1

Variants covered by this Declaration of Conformity.

C-VAC
C31-19-001
C31-19-002
C31-19-101
C31-19-102
C31-19-201
C31-19-202
C31-19-301
C31-19-302
C31-19-401
C31-19-402

Extenders
C31-15-145
C31-15-150

Needle electrodes
C31-11-060
C31-11-061
C31-11-062
C31-11-063
C31-11-064
C31-11-100
C31-11-101
C31-11-102
C31-11-120
C31-11-121
C31-11-122
C31-11-160
C31-11-161
C31-11-162

Blade electrodes
C31-10-060
C31-10-061
C31-10-062
C31-10-063
C31-10-064
C31-10-100
C31-10-101
C31-10-102
C31-10-103
C31-10-104
C31-10-120
C31-10-121
C31-10-122
C31-10-123
C31-10-124
C31-10-160
C31-10-161
C31-10-162
C31-10-163
C31-10-164
C31-10-200
C31-10-201
C31-10-202
C31-10-203
C31-10-204

Ball electrodes
C31-12-060
C31-12-061
C31-12-120
C31-12-121

Loop electrodes
C31-17-060
C31-17-061
C31-17-062
C31-17-063
C31-17-120
C31-17-121
C31-17-122
C31-17-123

Conization electrodes
C31-18-060
C31-18-061
C31-18-062
C31-18-063
C31-18-120
C31-18-121
C31-18-122
C31-18-123