EU Declaration of Conformity
CIMPAX® C-VAC

Manufacturer:	CIMPAX A/S Lille Pilevang 4 3550 Slangerup Denmark
SRN (Single Registration Number):	DK-MF-00010490
Notified Body:	3EC International a.s. Hraničná 18, 82105 Bratislava, Slovak Republic Notified Body No. 2265
Conformity Assessment Route:	Annex IX of the Regulation (EU) 2017/745
Certificate Numbers:	EC: 2023-MDR/QS-036
Basic UDI-DI:	5710314CVAC31J5
Brand/Trade Names:	CIMPAX® C-VAC Tornado CIMPAX® C-VAC Xtract Smoke ShieldTM CIMPAX® Extender CIMPAX® Electrodes Smoke ShieldTM Extender
Classification	Class: IIb Rule: 9
Intended Purpose:	CIMPAX® C-VAC with its accessories is used for cutting and coagulation of tissue structures, removal of smoke and aerosols during any form of surgery where electrosurgical pencils are used during the surgical procedure.

This declaration of conformity is issued under the sole responsibility of the manufacturer CIMPAX A/S. It is hereby declared that the device(s) covered by this declaration comply with the provisions of the Regulation (EU) MDR 2017/745 for medical devices and its transpositions into national laws of the Member States in which the device is distributed.

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Device(s) covered	
REF	**Trade name**
B31-19-001	CIMPAX® C-VAC TORNADO
B31-19-101	CIMPAX® C-VAC TORNADO
B31-20-001	CIMPAX® C-VAC XTRACT
B31-20-101	CIMPAX® C-VAC XTRACT
C31-19-001	CIMPAX® C-VAC TORNADO
C31-19-002	CIMPAX® C-VAC TORNADO
C31-19-003	CIMPAX® C-VAC TORNADO
C31-19-004	CIMPAX® C-VAC TORNADO
C31-19-101	CIMPAX® C-VAC TORNADO
C31-19-102	CIMPAX® C-VAC TORNADO
C31-19-103	CIMPAX® C-VAC TORNADO
C31-19-104	CIMPAX® C-VAC TORNADO
C31-19-201	CIMPAX® C-VAC TORNADO
C31-19-202	CIMPAX® C-VAC TORNADO
C31-19-203	CIMPAX® C-VAC TORNADO
C31-19-204	CIMPAX® C-VAC TORNADO
C31-19-301	CIMPAX® C-VAC TORNADO
C31-19-302	CIMPAX® C-VAC TORNADO
C31-19-303	CIMPAX® C-VAC TORNADO
C31-19-304	CIMPAX® C-VAC TORNADO
C31-19-401	CIMPAX® C-VAC TORNADO
C31-19-402	CIMPAX® C-VAC TORNADO
C31-19-403	CIMPAX® C-VAC TORNADO
C31-19-404	CIMPAX® C-VAC TORNADO
C31-19-501	CIMPAX® C-VAC TORNADO
C31-19-502	CIMPAX® C-VAC TORNADO
C31-19-503	CIMPAX® C-VAC TORNADO
C31-19-504	CIMPAX® C-VAC TORNADO
C31-19-601	CIMPAX® C-VAC TORNADO
C31-19-602	CIMPAX® C-VAC TORNADO
C31-19-603	CIMPAX® C-VAC TORNADO
C31-19-604	CIMPAX® C-VAC TORNADO
C31-20-001	CIMPAX® C-VAC XTRACT
C31-20-002	CIMPAX® C-VAC XTRACT
C31-20-003	CIMPAX® C-VAC XTRACT
C31-20-004	CIMPAX® C-VAC XTRACT

C31-20-101	CIMPAX® C-VAC XTRACT
C31-20-102	CIMPAX® C-VAC XTRACT
C31-20-103	CIMPAX® C-VAC XTRACT
C31-20-104	CIMPAX® C-VAC XTRACT
C31-20-201	CIMPAX® C-VAC XTRACT
C31-20-202	CIMPAX® C-VAC XTRACT
C31-20-203	CIMPAX® C-VAC XTRACT
C31-20-204	CIMPAX® C-VAC XTRACT
C31-20-301	CIMPAX® C-VAC XTRACT
C31-20-302	CIMPAX® C-VAC XTRACT
C31-20-303	CIMPAX® C-VAC XTRACT
C31-20-304	CIMPAX® C-VAC XTRACT
C31-20-401	CIMPAX® C-VAC XTRACT
C31-20-402	CIMPAX® C-VAC XTRACT
C31-20-403	CIMPAX® C-VAC XTRACT
C31-20-404	CIMPAX® C-VAC XTRACT
C31-20-501	CIMPAX® C-VAC XTRACT
C31-20-502	CIMPAX® C-VAC XTRACT
C31-20-503	CIMPAX® C-VAC XTRACT
C31-20-504	CIMPAX® C-VAC XTRACT
C31-20-601	CIMPAX® C-VAC XTRACT
C31-20-602	CIMPAX® C-VAC XTRACT
C31-20-603	CIMPAX® C-VAC XTRACT
C31-20-604	CIMPAX® C-VAC XTRACT
B31-15-145	CIMPAX® EXTENDER
B31-15-150	CIMPAX® EXTENDER
C31-15-145	CIMPAX® EXTENDER
C31-15-150	CIMPAX® EXTENDER
C31-10-060	CIMPAX® ELECTRODE BLADE
C31-10-061	CIMPAX® ELECTRODE BLADE
C31-10-062	CIMPAX® ELECTRODE BLADE
C31-10-063	CIMPAX® ELECTRODE BLADE
C31-10-064	CIMPAX® ELECTRODE BLADE
C31-10-100	CIMPAX® ELECTRODE BLADE
C31-10-101	CIMPAX® ELECTRODE BLADE
C31-10-102	CIMPAX® ELECTRODE BLADE
C31-10-103	CIMPAX® ELECTRODE BLADE
C31-10-104	CIMPAX® ELECTRODE BLADE
C31-10-120	CIMPAX® ELECTRODE BLADE

C31-10-121	CIMPAX® ELECTRODE BLADE
C31-10-122	CIMPAX® ELECTRODE BLADE
C31-10-123	CIMPAX® ELECTRODE BLADE
C31-10-124	CIMPAX® ELECTRODE BLADE
C31-10-160	CIMPAX® ELECTRODE BLADE
C31-10-161	CIMPAX® ELECTRODE BLADE
C31-10-162	CIMPAX® ELECTRODE BLADE
C31-10-163	CIMPAX® ELECTRODE BLADE
C31-10-164	CIMPAX® ELECTRODE BLADE
C31-10-200	CIMPAX® ELECTRODE BLADE
C31-10-201	CIMPAX® ELECTRODE BLADE
C31-10-202	CIMPAX® ELECTRODE BLADE
C31-10-203	CIMPAX® ELECTRODE BLADE
C31-10-204	CIMPAX® ELECTRODE BLADE
C31-11-060	CIMPAX® ELECTRODE NEEDLE
C31-11-061	CIMPAX® ELECTRODE NEEDLE
C31-11-062	CIMPAX® ELECTRODE NEEDLE
C31-11-063	CIMPAX® ELECTRODE MICRO-DISSECTION NEEDLE
C31-11-064	CIMPAX® ELECTRODE MICRO-DISSECTION NEEDLE
C31-11-100	CIMPAX® ELECTRODE NEEDLE
C31-11-101	CIMPAX® ELECTRODE NEEDLE
C31-11-102	CIMPAX® ELECTRODE NEEDLE
C31-11-120	CIMPAX® ELECTRODE NEEDLE
C31-11-121	CIMPAX® ELECTRODE NEEDLE
C31-11-122	CIMPAX® ELECTRODE NEEDLE
C31-11-160	CIMPAX® ELECTRODE NEEDLE
C31-11-161	CIMPAX® ELECTRODE NEEDLE
C31-11-162	CIMPAX® ELECTRODE NEEDLE
C31-12-060	CIMPAX® ELECTRODE BALL
C31-12-061	CIMPAX® ELECTRODE BALL
C31-12-120	CIMPAX® ELECTRODE BALL
C31-12-121	CIMPAX® ELECTRODE BALL
C31-17-060	CIMPAX® ELECTRODE LOOP
C31-17-061	CIMPAX® ELECTRODE LOOP
C31-17-062	CIMPAX® ELECTRODE LOOP
C31-17-063	CIMPAX® ELECTRODE LOOP
C31-17-064	CIMPAX® ELECTRODE LOOP
C31-17-120	CIMPAX® ELECTRODE LOOP
C31-17-121	CIMPAX® ELECTRODE LOOP

C31-17-122	CIMPAX® ELECTRODE LOOP
C31-17-123	CIMPAX® ELECTRODE LOOP
C31-17-124	CIMPAX® ELECTRODE LOOP
C31-18-060	CIMPAX® ELECTRODE CONIZATION
C31-18-061	CIMPAX® ELECTRODE CONIZATION
C31-18-062	CIMPAX® ELECTRODE CONIZATION
C31-18-063	CIMPAX® ELECTRODE CONIZATION
C31-18-120	CIMPAX® ELECTRODE CONIZATION
C31-18-121	CIMPAX® ELECTRODE CONIZATION
C31-18-122	CIMPAX® ELECTRODE CONIZATION
C31-18-123	CIMPAX® ELECTRODE CONIZATION
ESSMOKE001	Smoke Shield™
ESSMOKE101	Smoke Shield™
ESSMOKE001NS	Smoke Shield™
ESSMOKE101NS	Smoke Shield™
ESMOKEEXT145	Smoke Shield™ Extender
ESMOKEEXT150	Smoke Shield™ Extender

Place and Date of issue: Denmark, 10-11-2023

Name: Eva Hamplová

Title: QA Manager
on behalf of CEO

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