PROCEDURE APPROVALS

Note: Date of last approval will serve as the Approval Date for this document.

Name	Function	Signature	Date
Kathy Reddig	Regulatory	kreddig	05/26/2021

Digitally signed by Şarco Alexandru
Date: 2022.07.28 22:56:37 EEST
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity

Manufacturer: **Address:**	CONMED Corporation 525 French Road Utica, New York 13502 USA
European Auth. Rep.:	MDSS GmbH Schiffgraben 41 D-30175 Hannover Germany
Notified Body **Address:**	British Standards Institute (BSI) Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands
NB Identification #:	2797
Conformity Assessment:	Annex II, Sections 1-3 and 5, of the Directive 93/42/EEC on Medical Devices
EC Certificate Number:	CE587783
Device Classification:	Class IIb
Rule per Annex IX:	Rule 9
Product Family:	Electrosurgical Generators

Reference Number	Product Description	Date 1st CE Marked
60-8005-002	System 5000™ 100V-240V (Symbols Front Panel)	April 2002
60-8005-003	System 5000™ 100V-240V (English Front Panel)	April 2002
60-8015-SYS	System 5000™ 100V-240V (Symbols Front Panel), Mobile Pedestal, Upper Storage Basket, Lower Storage Basket, Monopolar Footswitch with 15' Cable, Bipolar Footswitch w/ 10' Cable	April 2002
60-8018-SYS	System 5000™ 100V-240V (English Front Panel), Mobile Pedestal, Upper Storage Basket, Lower Storage Basket, Monopolar Footswitch with 15' Cable, Bipolar Footswitch w/ 10' Cable	April 2002

List of Applied Harmonized Standards and years

EN 1041:2008 Information supplied by the manufacturer with medical devices

EN 60601-1:2006/A1:2013 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

EN 60601-2-2:2009 – Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment and high frequency surgical accessories

EN 62366:2008 – Medical devices – Application of usability engineering to medical devices

EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 14155:2011/AC:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements

EN ISO 14971:2019 Medical devices – Application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

We, the manufacturer, hereby declare that the medical devices listed on this declaration conform with the applicable provisions of EC Directive 93/42/EEC of 14June1993 concerning medical devices.

DOC Change History

Date	Rev.	Description of Change	Initials
18July13	A	Updated to new format; updated standards reference to refer to harmonized versions; corrected reference from ISO 14155-2 to EN ISO 14155:2011 (RA-2012-056); added EN ISO 15223-1:2012 (RA-2012-094); updated to EN ISO 14971:2012 (RA-2012-085).	LBA
31Mar14	B	Removed 60-8005-001; removed reference to EN ISO 15223-1.	LBA
25June14	C	Add reference to EN 980 and EN 62366. Update EN 60601-1-2:2007 to EN 60601-1-2:2007/AC2010 (see RA-2014-022)	JMV
08Oct18	D	Updated form; replaced EN 980 with EN ISO 15223-1:2016 per RA-2016-037; updated EN ISO 13485 to 2016 per audit; updated EN ISO 14155 to AC:2011 per RA-2012-056.	LBA
30Sep19	E	Updated EN 60601-1-2:2007/AC2010 to 2014 4th version	AX
30Apr2020	F	Updated to new template. Updated EN 60601-1 to A1:2013 per RA-2013-010, RA-2016-010 and RA-2017-011.	TLH
05/26/2021	G	Changed CE Mark number from 0086 to 2797. Updated EN ISO 14971:2012 to EN ISO 14971:2019 per ECN27437.	AX/TLH