

DOC. TITLE: Declaration of Conformity – Cardinal Health Multi-function Defibrillation Electrodes			
DOCUMENT NO:	RE00186800	REVISION:	1



DECLARATION OF CONFORMITY

We, Cardinal Health 200 LLC, declare that the products covered in this EU Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.

Declaration of Conformity Number	RE00186800
Technical Documentation Number	RE00168519
Manufacturer's Name	Cardinal Health 200, LLC also trading as Cardinal Health
Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA
Single Registration Number	US-MF-000006765
Authorized Representative's Name and Address	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Notified body's Name and Identification Number	Not Applicable
CE Certificate Number	Not Applicable
Product Category	Biomedical Electrodes
Basic UDI-DI	Refer to Attachment 1.
EMDN	External Cardioversion Defibrillator Electrode Pads [C020401]
Product Code, Trade name and Description	Refer to Attachment 1.
Intended Purpose	The Cardinal Health Multifunction Defibrillation Electrodes are intended to transfer energy from a cardiac defibrillator or pacemaker to the body of a patient for the purpose of defibrillation, synchronized cardioversion, pacing or for ECG monitoring.
Classification and Rule	Class I, Rule 1.
Common Specifications	Not Applicable
Where appropriate, add applicable Union legislation	Not Applicable
Conformity assessment	Self Declared

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SIGNATURE SECTION			
This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.			
Place of Issue	Waukegan, IL 60085 USA		
Signature	<i>Charmaine Wong</i>	<small>Electronically signed by: Charmaine Wong Reason: Approved Date: Jul 20, 2023 17:12 GMT+8</small>	Date Jul 20, 2023
Name and Function	Charmaine Wong Siting, Regulatory Affairs		

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ATTACHMENT 1

Product Code List

Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
22550A	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes	0630140000000000000020466	C020401	Class I, Rule I
22550P	Medi-Trace™ Cadence Pediatric Multi-Function Defibrillation Electrodes, Radiotransparent	063014000000000000001966Y	C020401	Class I, Rule I
22550PC	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrode, Pre-Connect	063014000000000000001966Y	C020401	Class I, Rule I
22550R	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes, Radiotransparent	0630140000000000000020364	C020401	Class I, Rule I
22660P	Medi-Trace™ Cadence, Pediatric Multi-Function Defibrillation Electrodes, Radiotransparent	063014000000000000002005W	C020401	Class I, Rule I
22660PC	Medi-Trace™ Cadence, Adult Multi-Function Defibrillation Electrodes, Pre-connect	0630140000000000000019874	C020401	Class I, Rule I
22660R	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes, Radiotransparent	063014000000000000002015Y	C020401	Class I, Rule I
22770P	Medi-Trace™ Cadence Pediatric Multi-Function Defibrillation Electrodes, Radiotransparent	0630140000000000000019772	C020401	Class I, Rule I
22770PC	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes, Pre-Connect	0630140000000000000019772	C020401	Class I, Rule I
22770R	Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes, Radiotransparent	0630140000000000000020262	C020401	Class I, Rule I
31319281	Kendall™ 1310P Multi-Function Defibrillation Electrodes	063014000000000000002636N	C020401	Class I, Rule I
31469219	Kendall™ 1410Z Multi-Function Defibrillation Electrodes	063014000000000000002646Q	C020401	Class I, Rule I
40000006	Kendall™ 1710H Multi-Function Defibrillation Electrodes	063014000000000000002646Q	C020401	Class I, Rule I







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Final Audit Report

2023-07-20

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