Registered Office & Legal Manufacturing Site	**Cardia International A.S.** Hersegade 34C, 4000 Roskilde, Denmark Phone: +45 7033 5353 Email – info@cardiaid.com Website - www.cardiaid.com
Corporate Office & Operations Site	**Cardia International B/V** Van der Burchstraat 40, 2132 RN Hoofddorp, The Netherlands Phone: +31 85 2016178
Single Registration number	**DK-MF-000002223**
European Representative:	Not Applicable
Trade Name	Defibrillation Electrodes– Adult Defibrillation Electrodes– Pediatric
Unique Device Identification:	Refer Attachment-1
Basic UDI-DI	Defibrillation Electrodes– Adult "B-08717931761239 Defibrillation Electrodes– Pediatric "B-08717931761246"

Product – Automated External Defibrillator								Serial No	
#	Brand	Model	Rule#	Class	LOT	Batch	Quantity	From	To
1.	Defibrillation Electrodes– Adult	CA-10ES	22	III	--	--	--	--	--
2.	Defibrillation Electrodes– Pediatric	CR-13P	22	III	--	--	--	--	--

GMDN Code	44771, External defibrillator electrode, adult, single-use 41587, External defibrillator electrode, paediatric, single-use
EMDN Code	Z12030580 DEFIBRILLATORS - HARDWARE ACCESSORIES C020401 External Cardioversion Defibrillator electrode pads
NBOG Code	MDA 0305
Conformity Assessment Route:	Annex IX
Declaration:	We declare that the manufacturer is solely responsible for; ● This declaration is at the sole discretion of the manufacturer ● We Cardia International ltd declare that the above-mentioned products meet the provisions of the REGULATION (EU) 2017/745, all prior amendments and as transposed into national laws in relevant Union legislation. All supporting documentation is retained under the premises of the manufacturer. ● The conformity assessment is in accordance with the procedure as documented in Annex IX of the REGULATION (EU) 2017/745. ● The manufacturing facility fulfills the requirements of ISO 13485:2016 and has been assessed by the Notified Body **IMQ S.p.A.**

Standards Applied:	EN ISO 13485: 2016+A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 10993-1: 2020, EN ISO 10993-5:2009, EN ISO 15223-1:2021, ISO/TR 24971:2020, ISO 10993-10:2021, ISO 20417:2021
Notified Body:	**IMQ S.p.A.** Via Quintiliano 43 - 20138 Milan – Italy **Notified Body number: 0051**
(EC) Certificate(s):	0070_MDR 0071_MDR
Place & Date of Issue:	Denmark, 10.09.2022
Signature: (Name & Designation)	Mike Vermin, Managing Director 

Registered Office & Legal Manufacturing Site	**Cardia International A.S.** Hersegade 34C, 4000 Roskilde, Denmark Phone: +45 7033 5353 Email – info@cardiaid.com Website - www.cardiaid.com
Corporate Office & Operations Site	**Cardia International B/V** Van der Burchstraat 40, 2132 RN Hoofddorp, The Netherlands Phone: +31 85 2016178
Single Registration number	**DK-MF-000002223**
European Representative:	Not Applicable
Product Name:	Automated External Defibrillator
Trade Name	CardiAid® Fully CardiAid® Semi Blostrupmoen® Fully Blostrupmoen® Semi
Registered trade mark or Brand Name:	CardiAid®, Blostrupmoen®
Unique Device Identification (UDI)	Refer Attachment-1
Basic UDI-DI	CardiAid® Semi-Automatic External Defibrillator- "B-08717931766036" CardiAid® Fully Automatic External Defibrillator- "B-08717931767033" Blostrupmoen® Semi-automatic External Defibrillator- "B-08717931762014" Blostrupmoen® Fully-automatic External Defibrillator- "B-08717931765015"

Product – Automated External Defibrillator								Serial No	
#	Brand	Model	Trade Name	Rule#	Class	Batch	Quantity	From	To
1.	CardiAid®	CT0207RS	CardiAid® Semi	22	III	--	--	--	--
2.	CardiAid®	CT0207RF	CardiAid® Fully	22	III	--	--	--	--
3.	Blostrupmoen®	BM0207RS	Blostrupmoen® Semi	22	III	--	--	--	--
4.	Blostrupmoen®	BM0207RF	Blostrupmoen® Fully Automatic	22	III	--	--	--	--

GMDN Code	47910, Non-rechargeable public semi-automated external defibrillator 48047, Non-rechargeable public automated external defibrillator
EMDN Code	Z12030501: Semi-automatic defibrillators Z12030503: Automatic defibrillators
NBOG Code	MDA 0305

Conformity Assessment Route:	Annex IX
Declaration:	We declare that the manufacturer is solely responsible for; ● This declaration is at the sole discretion of the manufacturer ● We Cardia International ltd declare that the above-mentioned products meet the provisions of the REGULATION (EU) 2017/745, all prior amendments and as transposed into national laws in relevant Union legislation. All supporting documentation is retained under the premises of the manufacturer. ● The conformity assessment is in accordance with the procedure as documented in Annex IX of the REGULATION (EU) 2017/745. ● The manufacturing facility fulfills the requirements of ISO 13485:2016 and has been assessed by the Notified Body **IMQ S.p.A.**
Standards Applied:	EN ISO 13485: 2016+A11:2021, EN ISO 14971:2019/A11:2021, EN 60601-1:2006+A1:2013+AC: 2014+ A12:2014+A2:2020, EN 60601-1-2:2015+A1:2020, EN ISO 10993-1: 2020, EN ISO 10993-5:2009, EN 60601-1-6: 2010+A1:2015+A2:2020, EN 62366: 2015+AC:2015+AC:2016+A1:2020, EN ISO 15223-1:2021, ISO/TR 24971:2020, ISO 10993-10:2021, ISO 20417:2021, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 CSV, IEC 60601-1-11:2015+AMD1:2020 CSV, IEC 60601-2-4:2010+AMD1:2018 CSV, IEC 60529: 1989/Amd2:2013/COR1: 2019, IEC 60068-2-6:2007, IEC 60068-2-64:2008+AMD1:2019 CSV, IEC 60068-2-27:2008
Notified Body:	**IMQ S.p.A.** Via Quintiliano 43 - 20138 Milan – Italy **Notified Body number: 0051**
(EC) Certificate(s):	0070_MDR 0071_MDR
Place & Date of Issue:	Denmark, 10.09.2022
Signature: (Name & Designation)	Mike Vermin, Managing Director