

ELECTRO-CAP INTERNATIONAL, INC

EU Declaration of Conformity

MANUFACTURER:

Electro-Cap International, Inc.
1011 W. Lexington Rd.
Eaton, OH 45320
USA
1 800 527 2193
SRN: T.B.D.

AUTHORIZED REPRESENTATIVE:

Electro-Cap Center, b.v.
Smederij 12
2421 MV Nieuwkoop
The Netherlands
31 172 572389
SRN: NL-AR-000002712

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Products: Electro-Cap Systems and related accessories for EEG testing

Models: See next page(s)

UDI-DI: See next page(s)

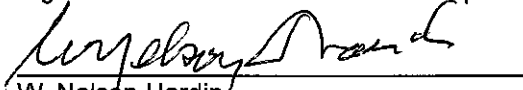
The medical devices described on this Declaration:

- Are in conformity with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices ("EU MDR"), as amended from time to time;
- Are Class I devices according to the criteria of Regulation 2017/745 Annex VIII, Rule 1;
- Are non-invasive medical devices not intended as sterile devices;
- Do not perform a measuring function;
- Are not reusable surgical instruments;
- Are therefore eligible for, and conform with, the conformity assessment route described in Article 52(7) of the EU MDR, as carried out by the Manufacturer;
- Do not require the intervention of a Notified Body, per applicable legislation;
- Meet the General Safety and Performance Requirements of Annex I of the EU MDR; and
- No Common Specifications were used in relation to this Declaration.

In addition, the medical devices described on this Declaration conform with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances.

The initial date of the CE Mark on Electro-Cap Systems was March 2, 1998.

Signed for and on behalf of Electro-Cap International, Inc.:


W. Nelson Hardin
President

Date of Issue: 5/21/21
Place of Issue: Eaton, Ohio
Expiration Date: 5/20/22

ELECTRO-CAP PRODUCT LIST WITH CODES

GTIN	Brand Name	Product Description
00811478010022	ELECTRO-CAP	CS2000-L/M STD SURGICAL CAP-LARGE/MEDIUM
00811478010039	ELECTRO-CAP	CS2000-M STD SURGICAL CAP-MEDIUM
00811478010046	ELECTRO-CAP	CS2000-M/SM STD SURGICAL CAP-MED/SMALL
00811478010053	ELECTRO-CAP	CS2000-L STD SURGICAL CAP-LARGE
00811478010060	ELECTRO-CAP	CS2000-XSM STD SURGICAL CAP-EX SMALL
00811478010169	ELECTRO-CAP	CS2005-L/M SURGICAL CAP W/EAR DROPS-L/MED
00811478010176	ELECTRO-CAP	CS2005-M/SM SURGICAL CAP W/EAR DROPS-MED/SM
00811478010510	ELECTRO-CAP	CS2000-SM STD SURGICAL CAP-SMALL
00811478010978	ELECTRO-CAP	CS2000-SM/XSM STD SURGICAL CAP-SM/XSM
00811478010985	ELECTRO-CAP	CS2005-SURGICAL CAP W/EAR DROPS-LARGE
00811478010992	ELECTRO-CAP	CS2005-M SURGICAL CAP W/EAR DROPS-MEDIUM
00811478011005	ELECTRO-CAP	CS2005-SM SURGICAL CAP W/EAR DROPS-SMALL
00811478011012	ELECTRO-CAP	CS2005-XSM SURGICAL CAP W/EAR DROPS-EX SMALL
00811478011210	ELECTRO-CAP	E1-DG/POZ-L ELECTRO-CAP W/POZ-LARGE
00811478011227	ELECTRO-CAP	E1-DG/POZ-L/M ELECTRO-CAP W/POZ-LARGE/MEDIUM
00811478011234	ELECTRO-CAP	E1-DG/POZ-M ELECTRO-CAP W/POZ-MEDIUM
00811478011241	ELECTRO-CAP	E1-DG/POZ-M/SM ELECTRO-CAP W/POZ-MEDIUM/SMALL
00811478011258	ELECTRO-CAP	E1-DG/POZ-SM ELECTRO-CAP W/POZ-SMALL
00811478011265	ELECTRO-CAP	E1-DG/POZ-SM/XS ELECTRO-CAP W/POZ-SMALL/EXSM
00811478011272	ELECTRO-CAP	E1-DG/POZ-XSM ELECTRO-CAP W/POZ-XSM
00811478011296	ELECTRO-CAP	E1-EASY2-L CADWELL EASY2 CAP-LARGE
00811478011302	ELECTRO-CAP	E1-EASY2-M CADWELL EASY2 CAP-MEDIUM
00811478011319	ELECTRO-CAP	E1-EASY2-SM CADWELL EASY2 CAP-SMALL
00811478011326	ELECTRO-CAP	E1-EASY2-XSM CADWELL EASY2 CAP-EX SMALL
00811478011333	ELECTRO-CAP	E1-L/M ELECTRO-CAP LGE/MED
00811478011340	ELECTRO-CAP	E1-SM ELECTRO-CAP SMALL
00811478011357	ELECTRO-CAP	E1-SM/XSM ELECTRO-CAP-SM/EX-SMALL
00811478011401	ELECTRO-CAP	E1-XSM ELECTRO-CAP-EX SMALL
00811478011456	ELECTRO-CAP	E1-M/SM ELECTRO-CAP MED/SMALL
00811478011593	ELECTRO-CAP	E2S EBA WITH SOCKETS

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00811478011746	ELECTRO-CAP	E3-L BODY HARNESS-LARGE
00811478011753	ELECTRO-CAP	E3-M BODY HARNESS-MEDIUM
00811478011760	ELECTRO-CAP	E3-SM BODY HARNESS-SMALL
00811478011784	ELECTRO-CAP	E4S QUICK INSERT ELEC-SOCKETS
00811478011814	ELECTRO-CAP	E5-6S EAR ELECTRODES - 6MM-SOCKETS
00811478011821	ELECTRO-CAP	E5-9S EAR ELEC - 9MM-SOCKETS
00811478011838	ELECTRO-CAP	E5-9S DROPS EAR ELEC3.5" DROPS
00811478011845	ELECTRO-CAP	E5-9S-10" DROPS EAR ELEC 10" DROPS
00811478011852	ELECTRO-CAP	E6 DISPOSABLE SPONGE DISKS
00811478011869	ELECTRO-CAP	E7 NEEDLE SYRINGE KIT
00811478011883	ELECTRO-CAP	E9 ELECTRO-GEL 16oz
00811478011890	ELECTRO-CAP	E10 ELECTRO-GEL 32oz
00811478011906	ELECTRO-CAP	E11 ELECTRO-GEL 128oz
00811478011937	ELECTRO-CAP	E12 HEAD MEASURING TAPE
00811478011944	ELECTRO-CAP	E13-L CAP STRAPS - LARGE
00811478011951	ELECTRO-CAP	E13-M CAP STRAPS - MEDIUM
00811478011968	ELECTRO-CAP	E13-SM CAP STRAPS - SMALL
00811478011975	ELECTRO-CAP	E13-XSM CAP STRAPS - EXTRA SMALL
00811478012026	ELECTRO-CAP	E17 BIO-POTENTIAL ELECTRODE
00811478012033	ELECTRO-CAP	E17S BIO-POTENTIAL ELEC-SOCKETS
00811478012200	ELECTRO-CAP	E19 SPARE ELECTRODE DISK
00811478012217	ELECTRO-CAP	E5-6S DROPS EAR ELEC3.5" DROPS
00811478012224	ELECTRO-CAP	E20 SPARE ELECTRODE MOUNTS
00811478012248	ELECTRO-CAP	E21-6S DISK ELECTRODES-6MM-SOCKET
00811478012262	ELECTRO-CAP	E21-9S DISK ELECTRODES-9MM-SOCKET
00811478012279	ELECTRO-CAP	E21-9S DROP DISK ELEC-9MM-3 1/2" DROPS
00811478012293	ELECTRO-CAP	E23-5 CHIN STRAPS-5 INCH
00811478012309	ELECTRO-CAP	E23-7 CHIN STRAPS-7 INCH
00811478012316	ELECTRO-CAP	E24 CHIN STRAP PADS
00811478012323	ELECTRO-CAP	E25 ADHESIVE ELECTRODE PADS
00811478012330	ELECTRO-CAP	E26 ORANGE STICKS

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00811478012361	ELECTRO-CAP	E28S ALLIGATOR CLIP ADAPTER-SOCKET
00811478012453	ELECTRO-CAP	E40 CONVERTER-PIN/SOCKET
00811478012507	ELECTRO-CAP	I1-1 INFA-CAP 1-20 ELECTRODES
00811478012514	ELECTRO-CAP	I1-2 INFA-CAP II-10 ELECTRODES
00811478012521	ELECTRO-CAP	I1-2-10ELEC INFA-CAP II-10 ELECTRODES
00811478012538	ELECTRO-CAP	I1-2-20ELEC INFA-CAP II-20 ELECTRODES
00811478012545	ELECTRO-CAP	I1-3 INFA-CAP III-10 ELECTRODES
00811478012552	ELECTRO-CAP	I1-3-10ELEC INFA-CAP III (10 ELECTRODES)
00811478012569	ELECTRO-CAP	I1-3-20ELEC INFA-CAP III (20 ELECTRODES)
00811478012576	ELECTRO-CAP	I2 INFA-BODY HARNESS
00811478012583	ELECTRO-CAP	I3 INFA-HEAD MEASURING TAPE
00811478012590	ELECTRO-CAP	I4 SKIN PREP PADS
00811478012606	ELECTRO-CAP	I5 INFA CHIN STRAPS
00811478012613	ELECTRO-CAP	INFA INFA SYSTEM
00811478012651	ELECTRO-CAP	INS-1 INSTRUCTION MANUAL
00811478012781	ELECTRO-CAP	E1-L ELECTRO-CAP-LARGE
00811478012798	ELECTRO-CAP	E1-M ELECTRO-CAP MEDIUM
00811478012828	ELECTRO-CAP	R1 REPAIR ELECTRO-CAP
00811478012835	ELECTRO-CAP	R2 REPAIR ELEC BOARD ADAPTER
00811478012859	ELECTRO-CAP	SYS-1S ELECTRO-CAP SYSTEM 1-SOCKETS
00811478012873	ELECTRO-CAP	SYS-2S ELECTRO-CAP SYSTEM 2-SOCKETS
00811478012897	ELECTRO-CAP	SYS-3S ELECTRO-CAP SYSTEM 3-SOCKETS
00811478012941	ELECTRO-CAP	DVD-1 INSTRUCTIONAL DVD
00811478010213	ELECTRO-CAP	E41 NEEDLE/SYRINGE KIT - LARGE