

EC Declaration of Conformity

No.: CNS-DC01

We

Manufacturer:

CNSAC MedShop GmbH
 Biebelrieder Str. 42
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SRN (Single Registration Number):

DE-MF-000024329

declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Name of the Device (s):

Device	Item Numbers	Basic UDI-DI (GMN)	CND/ EMDN
CNSAC Nasal, Nasal/Oral Cannula, filters, adapters	NC-002c, NC-002/30c, NC-002/150c, NC-002/210c, NC-007c, NC-017c, SEN115A, SEN118A, NC-130, TA-001/Kc, TA-001/80, TA-001/200, NC-113c, NC-114, NC-020, NC-021, NC-022, NC-028, TA80, TA200, 925235, 925236, TA500, NC250, NC255, NC260, TA220, NC-002f, NC-002/30f, NC-002/150f, NC-002/210f	426235615NC015T	R03010280
CNSAC EEG Cup Electrodes	CE-070c, CE-070/15c, CE-071c, CE-072c, CE-073c, CE-074c, CE-150c, CE-151c, CE-152c, CE-153c, CE-154c, CE-169, CE-169/16, CE-170, CE-171	426235615CE013Q	N01010299
ECG Electrodes	DE-008c, DE-009c, HSTR910, DE-220, DE-221, DE-230, DE-231, DE-231, DE-232, DE-233, DE-237, DE-241, DE-242, DE-244, DE-245	426235615EC013U	C020501
CNSAC Snap Button Cables	AE-001c, AE-020c, AE-021c, AE-022c, AE-023c, AE-024c, AE80BK, AE80RD, AE80YL, AE80GR, AE150BK, AE150RD, AE150YL, AE150GR	426235615AE013A	Z1399
lic2 Electrode Creams	CR-004/1c, CR-004c	426235615CR015R	Q010506
EEG-acp Paste	CR-050/1c, CR-050c	426235615CR015R	Q010506
EC2+ Electrode Cream	EC2+, EC2+ US	426235615CR015R	Q010506

Classification:

Class I (rule 1, Annex VIII)

Notified Body:

N/A

Notified Body Identification number:

N/A

Conformity assessment procedure:

Class I, non-sterile: Annex II and III

ISO 13485:2016 Medical device - Quality management systems

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

EN ISO 15223-1:2021 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

We hereby declare that the above products are in conformity with the essential requirements and provisions of the Regulation (EU) 2017/745 (MDR) according to Article 52 (7).

Place of issue: Theilheim, GERMANY

Date of issue: 2024-02-15

Signature:

Dr. Arash Kianian (CEO & QMR)

