

EU Declaration of Conformity

Hereby we declare in exclusive responsibility that below identified products fully comply with the regulations of the Medical Device Regulation (EU) 2017/745 (MDR) on medical devices.

To the best of our knowledge given the information provided by our suppliers, products are also in conformity with the Council Directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended by Directive (EU) 2015/863. Products are not made with natural rubber latex, and do not contain BPA.

waveguard™ EEG cap and accessories

Electrode caps, adapters and leads for recording of EEG signals

The product family consists of devices that are classified according to MDR Annex VIII, rule 1, as **CE class I**, and meets the applicable *General Safety and Performance Requirements* of the MDR Annex I.

We apply the conformity assessment procedure in accordance with MDR Annex IX and issue this declaration of conformity as manufacturer.

Products are marked with



The applicable sections of the following standards have been used as a basis for the conformity:

- IEC 60601-1:2005/A1:2012
- ISO 14971:2019
- ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-18:2020, ISO 10993-23:2021
- IEC 62366-1:2015
- ISO 15223-1:2021

This declaration DOC-QA-0001 is valid for product codes **REF** as stated in the appended product list.

The corresponding *Global Medical Device Nomenclature* (GMDN) code is: **63131**.


We are registered with HIBCC, with *Labeler Identification Code* (LIC): **B195**.

EUDAMED assigned our *Single Registration Number* (SRN): **DE-MF-000005560**.

The *notified body* involved in the assessment of our quality management system is:
TÜV NORD CERT GmbH, Am TÜV 1, D-45307 Essen, Germany: NB 0044.

Current certificate EN ISO 13485:2016 registration no. 44 221 211913, is valid until 2024-11-10.

Dated at Berlin, Germany, on the 31st day of January 2023.


Frank Zanow, CEO

eemagine Medical Imaging Solutions GmbH,
Gubener Straße 47, D-10243 Berlin,
Germany

Product list appended to the Declaration of Conformity for waveguard™ EEG cap and accessories

Intended purpose: waveguard EEG caps are intended for recording of electroencephalographic (EEG) signals, including event-related potentials (ERP) and evoked potentials (EP) on subjects or patients with intact scalp in combination with medical-grade EEG recording equipment (CE class IIa certified inside the European Union).

Caps	REF	Basic UDI-DI
(product family)		++B195waveguard9J
CA-001		++B195CA001P8
CA-002		++B195CA002PA
CA-003		++B195CA003PC
CA-004		++B195CA004PE
CA-005		++B195CA005PG
CA-010		++B195CA010P9
CA-061		++B195CA061PS
CA-065		++B195CA065Q2
CA-068		++B195CA068Q8
CA-069		++B195CA069QA
CA-081		++B195CA081PY
CA-082		++B195CA082Q2
CA-085		++B195CA085Q8
CA-086		++B195CA086QA
CA-088		++B195CA088QE
CA-089		++B195CA089QG
CA-090		++B195CA090PZ
CA-091		++B195CA091Q3
CA-100		++B195CA100PB
CA-101		++B195CA101PD
CA-102		++B195CA102PF
CA-103		++B195CA103PH
CA-104		++B195CA104PK
CA-105		++B195CA105PM
CA-106		++B195CA106PP
CA-107		++B195CA107PR
CA-108		++B195CA108PT
CA-109		++B195CA109PV
CA-110		++B195CA110PE
CA-111		++B195CA111PG
CA-112		++B195CA112PJ
CA-113		++B195CA113PL
CA-114		++B195CA114PN
CA-115		++B195CA115PQ
CA-116		++B195CA116PS
CA-118		++B195CA118PW
CA-119		++B195CA119PY
CA-121		++B195CA121PK
CA-122		++B195CA122PM
CA-123		++B195CA123PP
CA-124		++B195CA124PR
CA-125		++B195CA125PT
CA-126		++B195CA126PV
CA-129		++B195CA129Q3
CA-130		++B195CA130PL
CA-132		++B195CA132PQ
CA-133		++B195CA133PS
CA-134		++B195CA134PU
CA-136		++B195CA136PY
CA-137		++B195CA137Q2
CA-138		++B195CA138Q4
CA-139		++B195CA139Q6
CA-140		++B195CA140PP
CA-141		++B195CA141PR
CA-142		++B195CA142PT
CA-143		++B195CA143PV
CA-146		++B195CA146Q3
CA-147		++B195CA147Q5
CA-148		++B195CA148Q7
CA-149		++B195CA149Q9
CA-150		++B195CA150PS
CA-151		++B195CA151PU
CA-152		++B195CA152PW
CA-153		++B195CA153PY
CA-154		++B195CA154Q2
CA-155		++B195CA155Q4
CA-156		++B195CA156Q6
CA-157		++B195CA157Q8
CA-159		++B195CA159QC
CA-160		++B195CA160PV
CA-161		++B195CA161PX
CA-162		++B195CA162PZ
CA-163		++B195CA163Q3

Caps	REF	Basic UDI-DI
CA-164		++B195CA164Q5
CA-165		++B195CA165Q7
CA-166		++B195CA166Q9
CA-167		++B195CA167QB
CA-168		++B195CA168QD
CA-169		++B195CA169QF
CA-171		++B195CA171QJ
CA-172		++B195CA172Q4
CA-173		++B195CA173Q6
CA-174		++B195CA174Q8
CA-175		++B195CA175QA
CA-176		++B195CA176QC
CA-181		++B195CA181Q5
CA-185		++B195CA185QD
CA-191		++B195CA191Q8
CA-192		++B195CA192QA
CA-193		++B195CA193QC
CA-195		++B195CA195QG
CA-202		++B195CA202PL
CA-203		++B195CA203PN
CA-204		++B195CA204PQ
CA-205		++B195CA205PS
CA-206		++B195CA206PU
CA-207		++B195CA207PW
CA-208		++B195CA208PY
CA-209		++B195CA209Q2
CA-212		++B195CA212PP
CA-213		++B195CA213PR
CA-214		++B195CA214PT
CA-218		++B195CA218Q3
CA-220		++B195CA220PN
CA-221		++B195CA221PQ
CA-222		++B195CA222PS
CA-223		++B195CA223PU
CA-315		++B195CA315Q2
CA-316		++B195CA316Q4
CA-318		++B195CA318Q8
CA-319		++B195CA319QA
CA-326		++B195CA326Q7
CA-352		++B195CA352Q8
CA-356		++B195CA356QG
CA-359		++B195CA359QN
CA-401		++B195CA401PU
CA-411		++B195CA411PX
CA-412		++B195CA412PZ
CA-413		++B195CA413Q3
CA-420		++B195CA420PY
CA-421		++B195CA421Q2
CA-422		++B195CA422Q4
CA-430		++B195CA430Q3
CA-431		++B195CA431Q5
CA-432		++B195CA432Q7
CA-505		++B195CA505Q9
CS-301		++B195CS301TM
CS-305		++B195CS305TV
CS-311		++B195CS311TQ
CS-312		++B195CS312TS
CS-313		++B195CS313TU
CS-314		++B195CS314TW
CS-352		++B195CS352U6
CS-356		++B195CS356UE
CS-359		++B195CS359UL
CT-014		++B195CT014TN
CY-245		++B195CY245VE
CY-251		++B195CY251V9
CY-261		++B195CY261VC
CY-271		++B195CY271VF
CY-281		++B195CY281VJ
CY-401		++B195CY401V4
CY-431		++B195CY431VD
CY-432		++B195CY432VF
NA-245		++B195NA245TX
NA-255		++B195NA255U2
NA-261		++B195NA261TV

Caps	REF	Basic UDI-DI
NA-265		++B195NA265U5
NA-271		++B195NA271TY
NA-281		++B195NA281U3

Accessories	REF	Basic UDI-DI
XC-001		++B195XC001WV
XC-002		++B195XC002WX
XC-003		++B195XC003WZ
XC-004		++B195XC004X3
XC-005		++B195XC005X5
XC-100		++B195XC100WY
XC-101		++B195XC101X2
XC-103		++B195XC103X6
XC-104		++B195XC104X8
XC-106		++B195XC106XC
XC-108		++B195XC108XG
XC-109		++B195XC109XJ
XC-110		++B195XC110X3
XC-121		++B195XC121X8
XC-124		++B195XC124XE
XC-125		++B195XC125XG
XC-126		++B195XC126XJ
XC-131		++B195XC131XB
XC-133		++B195XC133XF
XC-136		++B195XC136XM
XC-140		++B195XC140XC
XC-141		++B195XC141XE
XC-151		++B195XC151XH
XC-152		++B195XC152XK
XC-153		++B195XC153XM
XC-160		++B195XC160XJ
XC-161		++B195XC161XL
XC-163		++B195XC163XQ
XC-210		++B195XC210X8
XC-240.(EOG GND REF)		++B195XC240XH
XC-301		++B195XC301XC
XC-302		++B195XC302XE
XC-305		++B195XC305XL
XC-351		++B195XC351XT
XC-425		++B195XC425XX
XC-810		++B195XC810Y6
XE-125.[1-5].(A C)		++B195XE125XW
XE-126		++B195XE126XY
XE-230		++B195XE230XU
XE-231		++B195XE231XW
XE-240		++B195XE240XX
XE-277		++B195XE277YN
XE-292		++B195XE292YJ
XE-293		++B195XE293YL
XE-294		++B195XE294YN
XE-295		++B195XE295YQ
XE-296		++B195XE296YS
XE-351		++B195XE351Y9
XE-383		++B195XE383YN
XE-384		++B195XE384YQ
XE-385.(C A)		++B195XE385YS
XE-391		++B195XE391YM
XS-260		++B195XS2603A
XS-270.(A B C D)		++B195XS2703D
XS-290		++B195XS2903K
XS-291		++B195XS2913M
XS-292		++B195XS2923P
XS-297		++B195XS2973Z

The size of CA/CS/CT/CY/NA caps is identified with the post-fix codes:

Post-fix	Size	Post-fix	Size
	(neonatal)	.06	B Baby
.01	N1	.07	I Infant
.02	N2	.08	C Child
.03	N3	.09	S Small
.04	N4	.10	M Medium
.05	N5	.11	L Large

Detailed size information in the user guide.