

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, as well as the relevant statutory requirements of the United Kingdom. 

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.

This corresponds to the same classification and relevant statutory requirements of the United Kingdom.

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/A2:2020
- 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/A1:2020
- ISO 15223-1:2021
- ISO 17664-2:2021

No Common Specifications are applicable.

This declaration DOC-QA-0001 is valid for product codes  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.

EN ISO 13485:2016	registration no. 44 221 211913	Valid until 2024-11-10
MDSAP ISO 13485:2016	registration no. 20-1601-M / by TÜV USA Inc.	Valid until 2024-10-28

Dated at Berlin, Germany, on the __15th__ day of __May__ 2024.


Frank Zanow, CEO

eemagine Medical Imaging Solutions GmbH,
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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	Caps	REF	Basic UDI-DI	Caps	REF	Basic UDI-DI	Accessories	REF	Basic UDI-DI
(product family)		++B195waveguard9J	CA-155		++B195CA155Q4	CS-315		++B195CS315TY	XC-001		++B195XC001WV
CA-001		++B195CA001P8	CA-156		++B195CA156Q6	CS-352		++B195CS352U6	XC-002		++B195XC002WX
CA-002		++B195CA002PA	CA-157		++B195CA157Q8	CS-356		++B195CS356UE	XC-003		++B195XC003WZ
CA-003		++B195CA003PC	CA-159		++B195CA159QC	CS-359		++B195CS359UL	XC-004		++B195XC004X3
CA-004		++B195CA004PE	CA-160		++B195CA160PV	CT-001		++B195CT001TD	XC-005		++B195XC005X5
CA-005		++B195CA005PG	CA-161		++B195CA161PX	CT-014		++B195CT014TN	XC-100		++B195XC100WY
CA-010		++B195CA010P9	CA-162		++B195CA162PZ	CY-245		++B195CY245VE	XC-101		++B195XC101X2
CA-061		++B195CA061PS	CA-163		++B195CA163Q3	CY-251		++B195CY251V9	XC-103		++B195XC103X6
CA-065		++B195CA065Q2	CA-164		++B195CA164Q5	CY-261		++B195CY261VC	XC-104		++B195XC104X8
CA-068		++B195CA068Q8	CA-165		++B195CA165Q7	CY-271		++B195CY271VF	XC-106		++B195XC106XC
CA-069		++B195CA069QA	CA-166		++B195CA166Q9	CY-281		++B195CY281VJ	XC-108		++B195XC108XG
CA-081		++B195CA081PY	CA-167		++B195CA167QB	CY-401		++B195CY401V4	XC-109		++B195XC109XJ
CA-082		++B195CA082Q2	CA-168		++B195CA168QD	CY-431		++B195CY431VD	XC-110		++B195XC110X3
CA-085		++B195CA085Q8	CA-169		++B195CA169QF	CY-432		++B195CY432VF	XC-121		++B195XC121X8
CA-086		++B195CA086QA	CA-171		++B195CA171Q2	NA-245		++B195NA245TX	XC-124		++B195XC124XE
CA-088		++B195CA088QE	CA-172		++B195CA172Q4	NA-255		++B195NA255U2	XC-125		++B195XC125XG
CA-089		++B195CA089QG	CA-173		++B195CA173Q6	NA-261		++B195NA261TV	XC-126		++B195XC126XJ
CA-090		++B195CA090PZ	CA-174		++B195CA174Q8	NA-265		++B195NA265U5	XC-131		++B195XC131XB
CA-091		++B195CA091Q3	CA-175		++B195CA175QA	NA-271		++B195NA271TY	XC-133		++B195XC133XF
CA-092		++B195CA092Q5	CA-176		++B195CA176QC	NA-281		++B195NA281U3	XC-136		++B195XC136XM
CA-093		++B195CA092Q7	CA-181		++B195CA181Q5	NA-301		++B195NA301TG	XC-140		++B195XC140XC
CA-094		++B195CA092Q9	CA-185		++B195CA185QD	NA-314		++B195NA314TR	XC-141		++B195XC141XE
CA-095		++B195CA092QB	CA-191		++B195CA191Q8				XC-151		++B195XC151XH
CA-100		++B195CA100PB	CA-192		++B195CA192QA				XC-152		++B195XC152XK
CA-101		++B195CA101PD	CA-193		++B195CA193QC				XC-153		++B195XC153XM
CA-102		++B195CA102PF	CA-195		++B195CA195QG				XC-160		++B195XC160XJ
CA-103		++B195CA103PH	CA-196		++B195CA195QJ				XC-161		++B195XC161XL
CA-104		++B195CA104PK	CA-202		++B195CA202PL				XC-163		++B195XC163XQ
CA-105		++B195CA105PM	CA-203		++B195CA203PN				XC-210		++B195XC210X8
CA-106		++B195CA106PP	CA-204		++B195CA204PQ				XC-240.(EOG GND REF)		++B195XC240XH
CA-107		++B195CA107PR	CA-205		++B195CA205PS				XC-301		++B195XC301XC
CA-108		++B195CA108PT	CA-206		++B195CA206PU				XC-302		++B195XC302XE
CA-109		++B195CA109PV	CA-207		++B195CA207PW				XC-305		++B195XC305XL
CA-110		++B195CA110PE	CA-208		++B195CA208PY				XC-351		++B195XC351XT
CA-111		++B195CA111PG	CA-209		++B195CA209Q2				XC-425		++B195XC425XX
CA-112		++B195CA112PJ	CA-212		++B195CA212PP				XC-810		++B195XC810Y6
CA-113		++B195CA113PL	CA-213		++B195CA213PR				XE-005.(01 02)		++B195XE005XK
CA-114		++B195CA114PN	CA-214		++B195CA214PT				XE-125.[1-5].(A C)		++B195XE125XW
CA-115		++B195CA115PQ	CA-218		++B195CA218Q3				XE-126		++B195XE126XY
CA-116		++B195CA116PS	CA-220		++B195CA220PN				XE-230		++B195XE230XU
CA-118		++B195CA118PW	CA-221		++B195CA221PQ				XE-231		++B195XE231XW
CA-119		++B195CA119PY	CA-222		++B195CA222PS				XE-240		++B195XE240XX
CA-121		++B195CA121PK	CA-223		++B195CA223PU				XE-277		++B195XE277YN
CA-122		++B195CA122PM	CA-315		++B195CA315Q2				XE-292		++B195XE292YJ
CA-123		++B195CA123PP	CA-316		++B195CA316Q4				XE-293		++B195XE293YL
CA-124		++B195CA124PR	CA-318		++B195CA318Q8				XE-294		++B195XE294YN
CA-125		++B195CA125PT	CA-319		++B195CA319QA				XE-295		++B195XE295YQ
CA-126		++B195CA126PV	CA-326		++B195CA326Q7				XE-296		++B195XE296YS
CA-129		++B195CA129Q3	CA-338		++B195CA338QE				XE-351		++B195XE351Y9
CA-130		++B195CA130PL	CA-352		++B195CA352QG				XE-383		++B195XE383YN
CA-132		++B195CA132PQ	CA-356		++B195CA356Q8				XE-384		++B195XE384YQ
CA-133		++B195CA133PS	CA-359		++B195CA359QN				XE-385.(C A)		++B195XE385YS
CA-134		++B195CA134PU	CA-401		++B195CA401PU				XE-391		++B195XE391YM
CA-136		++B195CA136PY	CA-411		++B195CA411PX				XS-260		++B195XS2603A
CA-137		++B195CA137Q2	CA-412		++B195CA412PZ				XS-270.(A B C D)		++B195XS2703D
CA-138		++B195CA138Q4	CA-413		++B195CA413Q3				XS-290		++B195XS2903K
CA-139		++B195CA139Q6	CA-420		++B195CA420PY				XS-291		++B195XS2913M
CA-140		++B195CA140PP	CA-421		++B195CA421Q2				XS-292		++B195XS2923P
CA-141		++B195CA141PR	CA-422		++B195CA422Q4				XS-297		++B195XS2973Z
CA-142		++B195CA142PT	CA-430		++B195CA430Q3						
CA-143		++B195CA143PV	CA-431		++B195CA431Q5						
CA-146		++B195CA146Q3	CA-432		++B195CA432Q7						
CA-147		++B195CA147Q5	CA-505		++B195CA505Q9						
CA-148		++B195CA148Q7	CA-506		++B195CA506QB						
CA-149		++B195CA149Q9	CS-301		++B195CS301TM						
CA-150		++B195CA150PS	CS-305		++B195CS305TV						
CA-151		++B195CA151PU	CS-311		++B195CS311TQ						
CA-152		++B195CA152PW	CS-312		++B195CS312TS						
CA-153		++B195CA153PY	CS-313		++B195CS313TU						
CA-154		++B195CA154Q2	CS-314		++B195CS314TW						

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

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

Detailed size information in the user guide.