

EU Declaration of Conformity

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

We herewith declare that the under-mentioned products meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. All supporting documentation is retained under the premises of the manufacturer. The device that is covered by the present declaration is in conformity with the Regulation (EU) 2017/745.

Product Name	ECG Lead Wire
Model Name	MEXXXXXX, MEXXXXXXXzX (Refer to Annex II)
Product Description	Electrocardiographic lead set, reusable
Intended Purpose	This medical device is intended to be used with electrocardiograph recorders/monitors that have diagnostic and monitoring purposes. This medical device is solely intended to be used between the electrode in contact with the patient's skin and the recording/monitoring device. This cabling facilitates conducts signals between the patient electrode and the monitoring device. Mednis' cables are limited by the Indications for Use of the connected recording/monitoring device This medical device is intended for medical purposes to connect an electrode in contact with a patient to a recording or monitoring device. The electrodes of this device are not intended to contact the patient.
GMDN Code	35562
SRN Code	KR-MF-000024165
GMDN Term Name	Electrocardiographic lead set, reusable
GMDN Definition	A collection of noninvasive devices intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest/limbs, to an electrocardiograph (ECG) machine or a patient monitoring system. It includes an insulated metal wire(s) with a detachable or permanently attached electrode, and may include a cable with connector; some types may be designed as a pre-configured array (e.g., EEG belt) to assist electrode placement. This is a reusable device.



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Basic UDI-DI of the device	8800179300015ZS
Risk Class of the device	Class I In accordance with the rule 1 of Classification Rules set out in Annex VIII of Regulation (EU) 2017/745
Harmonised Standards	Refer to Annex I
Manufacturer	MEDNIS Co., Ltd. 414(B) SK Twintech Tower, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, Korea
Authorised Representative	CMC Medical Devices & Drugs S.L. C/Horacio Lengo N° 18, CP 29006, Málaga, Spain

Place and date of issue: Seoul, Republic of Korea on 01 April 2022.



Yang gyeong-sig, President of MEDNIS Co., Ltd.
On behalf of MEDNIS Co., Ltd.



Annex I

Standard	Reference of the standard
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN 1041:2008	Information supplied by the manufacturer of medical devices



Annex II

List of ECG Lead Wire models_3IEAD-Linking (Page 1 / 8)								
ME30101	ME30201	ME30301	ME30401	ME30501	ME30601	ME30701	ME30801	
ME30102	ME30202	ME30302	ME30402	ME30502	ME30602	ME30702	ME30802	
ME30103	ME30203	ME30303	ME30403	ME30503	ME30603	ME30703	ME30803	
ME30104	ME30204	ME30304	ME30404	ME30504	ME30604	ME30704	ME30804	
ME30105	ME30205	ME30305	ME30405	ME30505	ME30605	ME30705	ME30805	
ME30106	ME30206	ME30306	ME30406	ME30506	ME30606	ME30706	ME30806	
ME30107	ME30207	ME30307	ME30407	ME30507	ME30607	ME30707	ME30807	
ME30108	ME30208	ME30308	ME30408	ME30508	ME30608	ME30708	ME30808	
ME30109	ME30209	ME30309	ME30409	ME30509	ME30609	ME30709	ME30809	
ME30110	ME30210	ME30310	ME30410	ME30510	ME30610	ME30710	ME30810	
ME30111	ME30211	ME30311	ME30411	ME30511	ME30611	ME30711	ME30811	
ME30112	ME30212	ME30312	ME30412	ME30512	ME30612	ME30712	ME30812	
ME30113	ME30213	ME30313	ME30413	ME30513	ME30613	ME30713	ME30813	
ME30114	ME30214	ME30314	ME30414	ME30514	ME30614	ME30714	ME30814	
ME30115	ME30215	ME30315	ME30415	ME30515	ME30615	ME30715	ME30815	
ME30116	ME30216	ME30316	ME30416	ME30516	ME30616	ME30716	ME30816	
ME30117	ME30217	ME30317	ME30417	ME30517	ME30617	ME30717	ME30817	
ME30118	ME30218	ME30318	ME30418	ME30518	ME30618	ME30718	ME30818	
List of ECG Lead Wire models_5IEAD-Linking (Page 2 / 8)								
ME50101	ME50201	ME50301	ME50401	ME50501	ME50601	ME50701	ME50801	
ME50102	ME50202	ME50302	ME50402	ME50502	ME50602	ME50702	ME50802	
ME50103	ME50203	ME50303	ME50403	ME50503	ME50603	ME50703	ME50803	
ME50104	ME50204	ME50304	ME50404	ME50504	ME50604	ME50704	ME50804	
ME50105	ME50205	ME50305	ME50405	ME50505	ME50605	ME50705	ME50805	
ME50106	ME50206	ME50306	ME50406	ME50506	ME50606	ME50706	ME50806	
ME50107	ME50207	ME50307	ME50407	ME50507	ME50607	ME50707	ME50807	
ME50108	ME50208	ME50308	ME50408	ME50508	ME50608	ME50708	ME50808	
ME50109	ME50209	ME50309	ME50409	ME50509	ME50609	ME50709	ME50809	
ME50110	ME50210	ME50310	ME50410	ME50510	ME50610	ME50710	ME50810	
ME50111	ME50211	ME50311	ME50411	ME50511	ME50611	ME50711	ME50811	
ME50112	ME50212	ME50312	ME50412	ME50512	ME50612	ME50712	ME50812	
ME50113	ME50213	ME50313	ME50413	ME50513	ME50613	ME50713	ME50813	
ME50114	ME50214	ME50314	ME50414	ME50514	ME50614	ME50714	ME50814	
ME50115	ME50215	ME50315	ME50415	ME50515	ME50615	ME50715	ME50815	
ME50116	ME50216	ME50316	ME50416	ME50516	ME50616	ME50716	ME50816	
ME50117	ME50217	ME50317	ME50417	ME50517	ME50617	ME50717	ME50817	
ME50118	ME50218	ME50318	ME50418	ME50518	ME50618	ME50718	ME50818	



List of ECG Lead Wire models_3IEAD-Separation Main(Page 3 / 8)								
ME310MA01	ME310MB01	ME310MC01	ME310LA01	ME310LB01	ME310LC01	ME310SA01	ME310SB01	ME310SC01
ME310MA02	ME310MB02	ME310MC02	ME310LA02	ME310LB02	ME310LC02	ME310SA02	ME310SB02	ME310SC02
ME310MA03	ME310MB03	ME310MC03	ME310LA03	ME310LB03	ME310LC03	ME310SA03	ME310SB03	ME310SC03
ME310MA04	ME310MB04	ME310MC04	ME310LA04	ME310LB04	ME310LC04	ME310SA04	ME310SB04	ME310SC04
ME310MA05	ME310MB05	ME310MC05	ME310LA05	ME310LB05	ME310LC05	ME310SA05	ME310SB05	ME310SC05
ME310MA06	ME310MB06	ME310MC06	ME310LA06	ME310LB06	ME310LC06	ME310SA06	ME310SB06	ME310SC06
ME310MA07	ME310MB07	ME310MC07	ME310LA07	ME310LB07	ME310LC07	ME310SA07	ME310SB07	ME310SC07
ME310MA08	ME310MB08	ME310MC08	ME310LA08	ME310LB08	ME310LC08	ME310SA08	ME310SB08	ME310SC08
ME310MA09	ME310MB09	ME310MC09	ME310LA09	ME310LB09	ME310LC09	ME310SA09	ME310SB09	ME310SC09
ME310MA10	ME310MB10	ME310MC10	ME310LA10	ME310LB10	ME310LC10	ME310SA10	ME310SB10	ME310SC10
ME310MA11	ME310MB11	ME310MC11	ME310LA11	ME310LB11	ME310LC11	ME310SA11	ME310SB11	ME310SC11
ME310MA12	ME310MB12	ME310MC12	ME310LA12	ME310LB12	ME310LC12	ME310SA12	ME310SB12	ME310SC12
ME310MA13	ME310MB13	ME310MC13	ME310LA13	ME310LB13	ME310LC13	ME310SA13	ME310SB13	ME310SC13
ME310MA14	ME310MB14	ME310MC14	ME310LA14	ME310LB14	ME310LC14	ME310SA14	ME310SB14	ME310SC14
ME310MA15	ME310MB15	ME310MC15	ME310LA15	ME310LB15	ME310LC15	ME310SA15	ME310SB15	ME310SC15
ME310MA16	ME310MB16	ME310MC16	ME310LA16	ME310LB16	ME310LC16	ME310SA16	ME310SB16	ME310SC16
ME310MA17	ME310MB17	ME310MC17	ME310LA17	ME310LB17	ME310LC17	ME310SA17	ME310SB17	ME310SC17
ME310MA18	ME310MB18	ME310MC18	ME310LA18	ME310LB18	ME310LC18	ME310SA18	ME310SB18	ME310SC18
List of ECG Lead Wire models_3IEAD-Separation Main(Page 4 / 8)								
ME319MA01	ME319MB01	ME319MC01	ME319LA01	ME319LB01	ME319LC01	ME319SA01	ME319SB01	ME319SC01
ME319MA02	ME319MB02	ME319MC02	ME319LA02	ME319LB02	ME319LC02	ME319SA02	ME319SB02	ME319SC02
ME319MA03	ME319MB03	ME319MC03	ME319LA03	ME319LB03	ME319LC03	ME319SA03	ME319SB03	ME319SC03
ME319MA04	ME319MB04	ME319MC04	ME319LA04	ME319LB04	ME319LC04	ME319SA04	ME319SB04	ME319SC04
ME319MA05	ME319MB05	ME319MC05	ME319LA05	ME319LB05	ME319LC05	ME319SA05	ME319SB05	ME319SC05
ME319MA06	ME319MB06	ME319MC06	ME319LA06	ME319LB06	ME319LC06	ME319SA06	ME319SB06	ME319SC06
ME319MA07	ME319MB07	ME319MC07	ME319LA07	ME319LB07	ME319LC07	ME319SA07	ME319SB07	ME319SC07
ME319MA08	ME319MB08	ME319MC08	ME319LA08	ME319LB08	ME319LC08	ME319SA08	ME319SB08	ME319SC08
ME319MA09	ME319MB09	ME319MC09	ME319LA09	ME319LB09	ME319LC09	ME319SA09	ME319SB09	ME319SC09
ME319MA10	ME319MB10	ME319MC10	ME319LA10	ME319LB10	ME319LC10	ME319SA10	ME319SB10	ME319SC10
ME319MA11	ME319MB11	ME319MC11	ME319LA11	ME319LB11	ME319LC11	ME319SA11	ME319SB11	ME319SC11
ME319MA12	ME319MB12	ME319MC12	ME319LA12	ME319LB12	ME319LC12	ME319SA12	ME319SB12	ME319SC12
ME319MA13	ME319MB13	ME319MC13	ME319LA13	ME319LB13	ME319LC13	ME319SA13	ME319SB13	ME319SC13
ME319MA14	ME319MB14	ME319MC14	ME319LA14	ME319LB14	ME319LC14	ME319SA14	ME319SB14	ME319SC14
ME319MA15	ME319MB15	ME319MC15	ME319LA15	ME319LB15	ME319LC15	ME319SA15	ME319SB15	ME319SC15
ME319MA16	ME319MB16	ME319MC16	ME319LA16	ME319LB16	ME319LC16	ME319SA16	ME319SB16	ME319SC16
ME319MA17	ME319MB17	ME319MC17	ME319LA17	ME319LB17	ME319LC17	ME319SA17	ME319SB17	ME319SC17
ME319MA18	ME319MB18	ME319MC18	ME319LA18	ME319LB18	ME319LC18	ME319SA18	ME319SB18	ME319SC18



List of ECG Lead Wire models_5IEAD-Separation Main(Page 5/ 8)								
ME510MA01	ME510MB01	ME510MC01	ME510LA01	ME510LB01	ME510LC01	ME510SA01	ME510SB01	ME510SC01
ME510MA02	ME510MB02	ME510MC02	ME510LA02	ME510LB02	ME510LC02	ME510SA02	ME510SB02	ME510SC02
ME510MA03	ME510MB03	ME510MC03	ME510LA03	ME510LB03	ME510LC03	ME510SA03	ME510SB03	ME510SC03
ME510MA04	ME510MB04	ME510MC04	ME510LA04	ME510LB04	ME510LC04	ME510SA04	ME510SB04	ME510SC04
ME510MA05	ME510MB05	ME510MC05	ME510LA05	ME510LB05	ME510LC05	ME510SA05	ME510SB05	ME510SC05
ME510MA06	ME510MB06	ME510MC06	ME510LA06	ME510LB06	ME510LC06	ME510SA06	ME510SB06	ME510SC06
ME510MA07	ME510MB07	ME510MC07	ME510LA07	ME510LB07	ME510LC07	ME510SA07	ME510SB07	ME510SC07
ME510MA08	ME510MB08	ME510MC08	ME510LA08	ME510LB08	ME510LC08	ME510SA08	ME510SB08	ME510SC08
ME510MA09	ME510MB09	ME510MC09	ME510LA09	ME510LB09	ME510LC09	ME510SA09	ME510SB09	ME510SC09
ME510MA10	ME510MB10	ME510MC10	ME510LA10	ME510LB10	ME510LC10	ME510SA10	ME510SB10	ME510SC10
ME510MA11	ME510MB11	ME510MC11	ME510LA11	ME510LB11	ME510LC11	ME510SA11	ME510SB11	ME510SC11
ME510MA12	ME510MB12	ME510MC12	ME510LA12	ME510LB12	ME510LC12	ME510SA12	ME510SB12	ME510SC12
ME510MA13	ME510MB13	ME510MC13	ME510LA13	ME510LB13	ME510LC13	ME510SA13	ME510SB13	ME510SC13
ME510MA14	ME510MB14	ME510MC14	ME510LA14	ME510LB14	ME510LC14	ME510SA14	ME510SB14	ME510SC14
ME510MA15	ME510MB15	ME510MC15	ME510LA15	ME510LB15	ME510LC15	ME510SA15	ME510SB15	ME510SC15
ME510MA16	ME510MB16	ME510MC16	ME510LA16	ME510LB16	ME510LC16	ME510SA16	ME510SB16	ME510SC16
ME510MA17	ME510MB17	ME510MC17	ME510LA17	ME510LB17	ME510LC17	ME510SA17	ME510SB17	ME510SC17
ME510MA18	ME510MB18	ME510MC18	ME510LA18	ME510LB18	ME510LC18	ME510SA18	ME510SB18	ME510SC18
List of ECG Lead Wire models_5IEAD-Separation Main(Page 6 / 8)								
ME519MA01	ME519MB01	ME519MC01	ME519LA01	ME519LB01	ME519LC01	ME519SA01	ME519SB01	ME519SC01
ME519MA02	ME519MB02	ME519MC02	ME519LA02	ME519LB02	ME519LC02	ME519SA02	ME519SB02	ME519SC02
ME519MA03	ME519MB03	ME519MC03	ME519LA03	ME519LB03	ME519LC03	ME519SA03	ME519SB03	ME519SC03
ME519MA04	ME519MB04	ME519MC04	ME519LA04	ME519LB04	ME519LC04	ME519SA04	ME519SB04	ME519SC04
ME519MA05	ME519MB05	ME519MC05	ME519LA05	ME519LB05	ME519LC05	ME519SA05	ME519SB05	ME519SC05
ME519MA06	ME519MB06	ME519MC06	ME519LA06	ME519LB06	ME519LC06	ME519SA06	ME519SB06	ME519SC06
ME519MA07	ME519MB07	ME519MC07	ME519LA07	ME519LB07	ME519LC07	ME519SA07	ME519SB07	ME519SC07
ME519MA08	ME519MB08	ME519MC08	ME519LA08	ME519LB08	ME519LC08	ME519SA08	ME519SB08	ME519SC08
ME519MA09	ME519MB09	ME519MC09	ME519LA09	ME519LB09	ME519LC09	ME519SA09	ME519SB09	ME519SC09
ME519MA10	ME519MB10	ME519MC10	ME519LA10	ME519LB10	ME519LC10	ME519SA10	ME519SB10	ME519SC10
ME519MA11	ME519MB11	ME519MC11	ME519LA11	ME519LB11	ME519LC11	ME519SA11	ME519SB11	ME519SC11
ME519MA12	ME519MB12	ME519MC12	ME519LA12	ME519LB12	ME519LC12	ME519SA12	ME519SB12	ME519SC12
ME519MA13	ME519MB13	ME519MC13	ME519LA13	ME519LB13	ME519LC13	ME519SA13	ME519SB13	ME519SC13
ME519MA14	ME519MB14	ME519MC14	ME519LA14	ME519LB14	ME519LC14	ME519SA14	ME519SB14	ME519SC14
ME519MA15	ME519MB15	ME519MC15	ME519LA15	ME519LB15	ME519LC15	ME519SA15	ME519SB15	ME519SC15
ME519MA16	ME519MB16	ME519MC16	ME519LA16	ME519LB16	ME519LC16	ME519SA16	ME519SB16	ME519SC16
ME519MA17	ME519MB17	ME519MC17	ME519LA17	ME519LB17	ME519LC17	ME519SA17	ME519SB17	ME519SC17
ME519MA18	ME519MB18	ME519MC18	ME519LA18	ME519LB18	ME519LC18	ME519SA18	ME519SB18	ME519SC18



List of ECG Lead Wire models_3, 5LEAD-Separation Lead wire(Page 7 / 8)								
ME311MA	ME311MB	ME311MC	ME311LA	ME311LB	ME311LC	ME311SA	ME311SB	ME311SC
ME312MA	ME312MB	ME312MC	ME312LA	ME312LB	ME312LC	ME312SA	ME312SB	ME312SC
ME313MA	ME313MB	ME313MC	ME313LA	ME313LB	ME313LC	ME313SA	ME313SB	ME313SC
ME314MA	ME314MB	ME314MC	ME314LA	ME314LB	ME314LC	ME314SA	ME314SB	ME314SC
ME315MA	ME315MB	ME315MC	ME315LA	ME315LB	ME315LC	ME315SA	ME315SB	ME315SC
ME316MA	ME316MB	ME316MC	ME316LA	ME316LB	ME316LC	ME316SA	ME316SB	ME316SC
ME317MA	ME317MB	ME317MC	ME317LA	ME317LB	ME317LC	ME317SA	ME317SB	ME317SC
ME318MA	ME318MB	ME318MC	ME318LA	ME318LB	ME318LC	ME318SA	ME318SB	ME318SC
ME511MA	ME511MB	ME511MC	ME511LA	ME511LB	ME511LC	ME511SA	ME511SB	ME511SC
ME512MA	ME512MB	ME512MC	ME512LA	ME512LB	ME512LC	ME512SA	ME512SB	ME512SC
ME513MA	ME513MB	ME513MC	ME513LA	ME513LB	ME513LC	ME513SA	ME513SB	ME513SC
ME514MA	ME514MB	ME514MC	ME514LA	ME514LB	ME514LC	ME514SA	ME514SB	ME514SC
ME515MA	ME515MB	ME515MC	ME515LA	ME515LB	ME515LC	ME515SA	ME515SB	ME515SC
ME516MA	ME516MB	ME516MC	ME516LA	ME516LB	ME516LC	ME516SA	ME516SB	ME516SC
ME517MA	ME517MB	ME517MC	ME517LA	ME517LB	ME517LC	ME517SA	ME517SB	ME517SC
ME518MA	ME518MB	ME518MC	ME518LA	ME518LB	ME518LC	ME518SA	ME518SB	ME518SC
List of ECG Lead Wire models_10LEAD (Page 8/ 8)								
ME12101	ME12201	ME12301	ME12401	ME12501	ME12601			
ME12102	ME12202	ME12302	ME12402	ME12502	ME12602			
ME12103	ME12203	ME12303	ME12403	ME12503	ME12603			
ME12104	ME12204	ME12304	ME12404	ME12504	ME12604			
ME12105	ME12205	ME12305	ME12405	ME12505	ME12605			
ME12106	ME12206	ME12306	ME12406	ME12506	ME12606			
ME12107	ME12207	ME12307	ME12407	ME12507	ME12607			
ME12108	ME12208	ME12308	ME12408	ME12508	ME12608			
ME12109	ME12209	ME12309	ME12409	ME12509	ME12609			
ME12110	ME12210	ME12310	ME12410	ME12510	ME12610			
ME12111	ME12211	ME12311	ME12411	ME12511	ME12611			
ME12112	ME12212	ME12312	ME12412	ME12512	ME12612			
ME12113	ME12213	ME12313	ME12413	ME12513	ME12613			
ME12114	ME12214	ME12314	ME12414	ME12514	ME12614			
ME12115	ME12215	ME12315	ME12415	ME12515	ME12615			
ME12116	ME12216	ME12316	ME12416	ME12516	ME12616			