

EU DECLARATION OF CONFORMITY

Manufacturer: Medico Electrodes International Ltd.
Plot 142A/11, 12, 27, 28 & 29, Noida Special Economic Zone, Noida,
Uttar Pradesh, 201305, India.

SRN: IN-MF-000021002

Product Name: Ambu® WhiteSensor

Model Name/Type: Various (Annexure-01 for product details)

Intended Purpose: Electrocardiograph Electrodes (ECG Electrodes)

Basic UDI-DI: 89060352820210101DL

Device Classification: Class I (in accordance with Annex VIII, Rule 1- Non-invasive devices of EU MDR 2017/745)

Packaging: Various

GMDN Code: 35035 (Single Use ECG Electrode)

We Herewith Declare In Our Own Responsibility that The Above-Mentioned Products Meet The General Safety and Performance Requirements, Annex I, of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices. All supporting documentation and Technical file is retained under the premises of the manufacturer (Head of Quality Department) & Authorized European Representative and will be kept at disposal of the Notified Body and Competent Authorities for a period of ten years from the production date of the device.

We further declare that a suitable procedure is maintained which grants the application of the post-marketing surveillance procedure required by EU MDR 2017/745.

General applicable regulation(s): Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Referenced standard(s): ANSI/AAMI EC12:2000

Authorized European Representative: Medico Electrodes Ltd.
Blvd. Saint-Michel 65/6
1040 Brussels, Belgium
SRN: BE-AR-000020093

www.medicoelectrodes.com

Person keeping the technical documentation: Amit Seth, Vice-President.

Signed
For Medico Electrodes International Ltd.,



Date: **19-05-2022**
Place: NOIDA, U.P., INDIA

On the basis of this declaration, the product packaging will bear the following marking:



Annexure – 01

S.No.	Ambu References	Medico References
1.	WS-00-S/3	MSGLT-05M
2.	WS-00-S/4	MSGLT-05M
3.	WS-00-S/5	MSGLT-05M
4.	WS-00-S/10	MSGLT-05M
5.	WS-00-S/30	MSGLT-05M
6.	WS-00-S/50	MSGLT-05M
7.	WS-00-S/L5/50	MSGLT-05M
8.	4500M	MLGLT-03RT
9.	4560M	MLGLT-38
10.	4570M	MLGLT-38RT
11.	4500M-H	MLGLT-03
12.	4535M	MLGST-06
13.	WS-00-S/RT/50	MSGLT-05MRT
14.	4831Q	MSGLT-39F
15.	4841P	MSGLT-40FRT
16.	7841P	MSGLT-40TRT
17.	4540	MLGST-194RT
18.	4200	MSGST-06M
19.	4300	MSGLT-05MG
20.	4530	MLGST-193RT
21.	4440	MLGLT-15CRT
22.	WSP25-00-S/50	MSGST-27
23.	WSP30-00-S/50	MSGST-37
24.	4500M-H/10	MLGLT-03
25.	4440/5	MLGLT-15CRT
26.	4440/3	MLGLT-15CRT
27.	4500M-H/5	MLGLT-03
28.	4500M-H/3	MLGLT-03
29.	4500M/5	MLGLT-03RT
30.	4500M/3	MLGLT-03RT
31.	4535M/5	MLGST-06
32.	4535M/3	MLGST-06
33.	7841P/5	MSGLT-40TRT
34.	7841P/3	MSGLT-40TRT
35.	WS-00-S/RT/5	MSGLT-05MRT
36.	WS-00-S/RT/3	MSGLT-05MRT
37.	WSP30-00-S/5	MSGST-37
38.	WSP30-00-S/3	MSGST-37
39.	4535M/30	MLGST-06
40.	3351-00-S/RT/50	MSGLT-09RT
41.	2742-00-C/100	OTL-4227
42.	3552-00-A/50	OTL-5235-S4
43.	2837	TL-3728
44.	3552-00-S/60	OTL-5235-S
45.	3552-00-C/100	OTL-5235
46.	3245D/RT/60	TSL-4532
47.	2742-00-S/RT/60	OTL-4227-RT
48.	2742-00-A/50	OTL-4227-S4
49.	6060-00-S/30	OTL-5235-S60
50.	2742-00-S/60	OTL-4227-S
51.	3552-00-S/RT/60	OTL-5235-RT
52.	5050-00-S/50	OTL-4227-S50
53.	4242-00-S/50	OTL-4227-S42
54.	3552DUAL/RT/50	OTSL-5235-RT

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55.	4242-00-S/10	OTL-4227-S42
56.	4242-00-S/5	OTL-4227-S42
57.	4242-00-S/3	OTL-4227-S42
58.	5050-00-S/10	OTL-4227-S50
59.	5050-00-S/5	OTL-4227-S50
60.	5050-00-S/3	OTL-4227-S50
61.	0215M	3413MED
62.	0315M	3521MED
63.	0415M	3423MED
64.	0715M	3426MED