

CE DECLARATION OF CONFORMITY
According to the Annex IX of the Directive 93/42/EEC



The undersigned **FOR.ME.SA. SRL**, manufacturer of following Medical Devices, with location in Via Don Minzoni 52/A, 43015 Noceto (PR)

DECLARES

Under ou responsibility that the followint Devides satisfy Essential Requirements required from Annex I Directive 93/42/EEC:

<i>Description</i>	<i>Code</i>	<i>CLASS</i>	<i>CND</i>	<i>GMDN</i>	<i>RDM</i>
Nasal aspirator	FOR.70-545	I	V0299	n.d.	36492/R
Foam biadhesive strip for fixing the external male catheters	FOR.007.999	I	U0780	n.d.	915735/R
Hot water bottle	70-501.04 (for children)	I	V0401	12042	57431/R
	70-501.40 (one side ribbed in polybag - Deluxe)	I	V0401	12042	588987/R
	70-501-39 (two side ribbed in polybag - Deluxe)	I	V0401	12042	589007/R
	70-501.10 (one side ribbed in polybag - Conventional)	I	V0401	12042	1011877/R
	70-501.11 (two side ribbed in polybag - Conventional)	I	V0401	12042	381383/R
	70-501.07 (with cover)	I	V0401	12042	-
Ice bag	70-503.04 (oval)	I	M9001	12082	19907/R
	70-503.05 (cervical)	I	M9001	12082	19913/R
	70-503.01 (diam. 20 round)	I	M9001	12082	19903/R
	70-503.02 (diam. 25 round)	I	M9001	12082	44199/R
	70-503.03 (diam. 28 round)	I	M9001	12082	44203/R
	70-503.11 (TEAM blue meas. 25 in case)	I	M9001	12082	589048/R
	70-503.11/S (TEAM blue meas. 25 in polybag)	I	M9001	12082	1380121/R
	70-503.12 (TEAM blue meas. 28 in case)	I	M9001	12082	589055/R
	70-503.12/S (TEAM blue meas. 28 in polybag)	I	M9001	12082	1380122/R
	70-503.13 (TEAM blue meas. 31 in case)	I	M9001	12082	589050/R
	70-503.13/S (TEAM blue meas. 31 in polybag)	I	M9001	12082	1380123/R
	70-503.08 (AVANA meas. 25 in case)	I	M9001	12082	19947/R
	70-503.08/S (AVANA meas. 25 in polybag)	I	M9001	12082	-
70-503.09 (AVANA mis. 28 in astuccio)	I	M9001	12082	44171/R	
70-503.09/S (AVANA mis.28 in sacchetto)	I	M9001	12082	-	



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FOR.ME.SA srl
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43015 Noceto (PR) Italia
Tel. +39 0521.628482
Fax. +39 0521.620382
www.formesa.it
e-mail: info@formesa.it
Cod. Fisc. e Part. IVA: IT01714420344
R.E.A. Parma: 173353
PEC: formesa@arubapec.it
Cod. Mecc.: PR 017790



REG. N. 3685-A
UNI EN ISO 9001:2008
UNI CEI EN ISO 13485:2012

	70-503.10 (AVANA mis. 31 in astuccio) 70-503.10/S (AVANA mis.31 in sacchetto)	I I	M9001 M9001	12082 12082	44176/R -
Fabric cuff for sphygmomanometer	FOR.004.014 (fabric cuff with velcro and ring)	I	Z12040180	n.d.	58453/R
	FOR.004.015 (with velcro and ring)	I	Z12040180	n.d.	70613/R
	FOR.004.017 (inflatable cuff with velcro and ring 1 way)	I	Z12040180	n.d.	70627/R
	FOR.004.018 (inflatable cuff with velcro and ring 2 ways)	I	Z12040180	n.d.	71494/R
	FOR.004.019 (inflatable cuff for obese people with velcro and ring 1 way) FOR.004.020 (inflatable cuff for obese people with velcro and ring 2 ways)	I I	Z12040180 Z12040180	n.d. n.d.	71518/R 71520/R
Spare parts for sphygmomanometer	FOR.004.010 (adult 1 way) FOR.004.011 (adult 2 ways)	I I	Z12040180 Z12040180	34978 34978	58395/R 72554/R
	FOR.004.012 (pediatric 1 way) FOR.004.013 (pediatric 2 ways)	I I	Z12040180 Z12040180	34978 34978	72560/R 72564/R
	FOR.004.029 (obese people 1 way) FOR.004.030 (obese people 2 ways)	I I	Z12040180 Z12040180	34978 34978	72585/R 72591/R
Anal cannula	FOR.005.006	I	U0899	n.d.	91968/R
Vaginal cannula	FOR.005.005	I	U0899	n.d.	91938/R
External latex catheters in polybag	FOR.007.025 (diam. 25 mm)		U070201	34929	29559/R
	FOR.007.030 (diam. 30 mm)	I	U070201	34929	38009/R
	FOE.007.035 (diam. 35 mm)		U070201	34929	38014/R
External silicone catheters	FOR.007.S25 (diam. 25 mm)		U070201	34929	1368176/R
	FOR.007.S30 (diam. 30 mm)	I	U070201	34929	1368177/R
	FOE.007.S35 (diam. 35 mm)		U070201	34929	1368178/R
Invalid ring - CONVENTIONAL	70-507.01 (diam. 35 cm)	I	V0803	41058	19960/R
	70-507.02 (diam. 40 cm)	I	V0803	41058	44231/R
	70-507.03 (diam. 43 cm)	I	V0803	41058	44289/R
	70-507.04 (diam. 45 cm)		V0803	41058	44328/R
Invalid ring with inflator inserted (DELUXE) with pump	70-506.01P (diam.35 cm)	I	V0803	41058	1471907/R
	70-506.02P (diam 40 cm)	I	V0803	41058	1471908/R
	70-506.03P (diam 43 cm)	I	V0803	41058	1471909/R
	70-506.04P (diam. 45 cm)	I	V0803	41058	1471910/R
Invalid ring - TEAM (DELUXE) without pump	70-508.01 (diam. 35 cm)	I	V0803	41058	589030/R
	70-508.02 (diam. 40 cm)	I	V0803	41058	589031/R
	70-508.03 (diam. 43 cm)	I	V0803	41058	589033/R
	70-508.04 (diam. 45 cm)	I	V0803	41058	589034/R
Polyurethane foam pad	70-506.06 (operhorse shoe)	I	V0803	41058	544727/R
	70-506.07 (round)	I	V0803	41058	1024166/R
Soft cervical collar	40-135.01 (meas. small)	I	Y060312	41039	36612/R
	40-135.02 (meas. medium)	I	Y060312	41039	57562/R
	40-132.03 (meas. large)	I	Y060312	41039	57574/R
	40-132.04 (meas. extra large)	I	Y060312	41039	57584/R
	40-135.05 (meas. small) Deluxe	I	Y060312	41039	1476259/R
	40-135.06 (meas. medium) Deluxe	I	Y060312	41039	1476260/R
	40-132.07 (meas. large) Deluxe	I	Y060312	41039	1476261/R
	40-132.08 (meas. extra large) Deluxe	I	Y060312	41039	1476262/R
Rigid cervical collar	40-142.01 (meas. small)	I	Y060312	41039	36949/R
	40-142.02 (meas. medium)	I	Y060312	41039	57600/R



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	40-142.03 (meas. large)	I	Y060312	41039	57603/R
	40-142.04 (meas. extra large)	I	Y060312	41039	57613/R
	40-142.13 (meas. small) Deluxe	I	Y060312	41039	1476181/R
	40-142.14 (meas. medium) Deluxe	I	Y060312	41039	1476187/R
	40-142.15 (meas. large) Deluxe	I	Y060312	41039	1476194/R
	40-142.16 (meas. extra large) Deluxe	I	Y060312	41039	1476196/R
Semirigid cervical collar	40-138.01 (meas. small)	I	Y060312	41039	381371/R
	40-138.02 (meas. medium)	I	Y060312	41039	381372/R
	40-138.03 (meas. large)	I	Y060312	41039	381373/R
	40-138.04 (meas. extra large)	I	Y060312	41039	381375/R
Cervical collar "Philadelphia"	40-142.05 (meas. small)	I	Y060312	41039	-
	40-142.06 (meas. medium)	I	Y060312	41039	-
	40-142.07 (meas. large)	I	Y060312	41039	-
	40-142.08 (meas. extra large)	I	Y060312	41039	-
Enema irrigator	FOR.005.001	I	U0899	32616	V2W5DF/R
Hot-cold gel	FOR.010.034 (14x18 cm pack TNT)	I	M030504	37240	VHP1BU/R
	FOR.010.034/A (14x18 cm pack TNT in case)	I	M030504	37240	VHP1BG/R
	FOR.010.047 (14x24 cm with velcro)	I	M030504	37240	VJ41RZ/R
	FOR.010.047/A (14x24 cm with velcro in case)	I	M030504	37240	VJK1HN/R
Cotton gloves for skin allergies	FOR.010.0106/0 (meas. 6.0)	I	T0199	18039	V4XY2U/R
	FOR.010.0106/5 (meas. 6.5)	I	T0199	18039	V4XY36/R
	FOR.010.0107/0 (meas. 7.0)	I	T0199	18039	V4XY3L/R
	FOR.010.0107/5 (meas. 7.5)	I	T0199	18039	V4XY3Y/R
	FOR.010.0108/0 (meas. 8.0)	I	T0199	18039	V4XY4B/R
	FOR.010.0108/5 (meas. 8.5)	I	T0199	18039	V4XY4D/R
	FOR.010.0109/0 (meas. 9.0)	I	T0199	18039	V4XY4S/R
Shoulder immobilizer	40-150.01 (meas. small)	I	Y060699	43262	381319/R
	40-150.02 (meas. medium)	I	Y060699	43262	381328/R
	40-150.03 (meas. large)	I	Y060699	43262	381330/R
Cotton sheet with rings	FOR.011.09 (misura 50x70 cm)	I	T04010201	35339	1252338/R
	FOR.011.10 (misura 90x140 cm)	I	T04010201	35339	1252344/R
	FOR.011.11 (misura 130x140 cm)	I	T04010201	35339	1252345/R
	FOR.011.12 (misura 200x140 cm)	I	T04010201	35339	1252346/R
	FOR.011.13 (misura 230x140 cm)	I	T04010201	35339	1252347/R
Cotton sheet with elastics	FOR.011.14 (misura 50x70 cm)	I	T04010201	35339	1421268/R
	FOR.011.15 (misura 90x140 cm)	I	T04010201	35339	1421274/R
	FOR.011.16 (misura 130x140 cm)	I	T04010201	35339	1421281/R
	FOR.011.17 (misura 200x140 cm)	I	T04010201	35339	1421283/R
	FOR.011.18 (misura 230x140 cm)	I	T04010201	35339	1421286/R
Rubber sheet with rings	FOR.011.01 (misura 60x90 cm)	I	T04010201	35339	20002/R
	FOR.011.02 (misura 90x70 cm)	I	T04010201	35339	57478/R
	FOR.011.03 (misura 90x90 cm)	I	T04010201	35339	57490/R
	FOR.011.04 (misura 90x100 cm)	I	T04010201	35339	57498/R
	FOR.011.05 (misura 90x120 cm)	I	T04010201	35339	57522/R
	FOR.011.06 (misura 90x150 cm)	I	T04010201	35339	57530/R
	FOR.011.07 (misura 90x180 cm)	I	T04010201	35339	57466/R
	FOR.011.08 (misura 90x200 cm)	I	T04010201	35339	57474/R
Gel face mask	FOR.010.101	I	V9099	n.d.	1039926/R
Gel eyes mask	FOR.010.099	I	V9099	n.d.	88293/R
White plastic mask for adults in case	FOR.002.008	I	R03010301	n.d.	1153029/R
Silicone mask for resuscitator	70-555-16 (misura 00)	I	R03020201	n.d.	64910/R
	70-555-17 (misura 0)	I	R03020201	n.d.	94799/R



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	70-555-18 (misura 1)	I	R03020201	n.d.	64802/R
	70-555-19 (misura 2)	I	R03020201	n.d.	64804/R
	70-555-20 (misura 3)	I	R03020201	n.d.	64807/R
	70-555-21 (misura 4)	I	R03020201	n.d.	64808/R
	70-555-22 (misura 5)	I	R03020201	n.d.	64809/R
Air cushion mask	70-555-46 (neonatal, white)	I	R03010199	n.d.	1362030/R
	70-555-47 (pink, infant)	I	R03010199	n.d.	1362032/R
	70-555-48 (yellow, pediatric)	I	R03010199	n.d.	1362034/R
	70-555-49 (green, child)	I	R03010199	n.d.	1362036/R
	70-555-50 (red, small adult)	I	R03010199	n.d.	1362038/R
	70-555-51 (blue, adult)	I	R03010199	n.d.	1362040/R
Bed pan	FOR.001.009	I	Y091299	34867	28157/R
Silicone resuscitator	70-555-01 (adult with accessories)	I	R03020201	17591	20018/R
	70-555-02 (pediatric with accessories)	I	R03020201	17591	57773/R
	70-555-03 (infant with accessories)	I	R03020201	17591	57780/R
	70-555-04 (adult without accessories)	I	R03020201	17591	76556/R
	70-555-05 (pediatric without accessories)	I	R03020201	17591	76570/R
	70-555-06 (infant without accessories)	I	R03020201	17591	76598/R
Finger cot	40-160.01 (meas. small)	I	Y060609	43817	792727/R
	40-160.02 (meas. medium)	I	Y060609	43817	792747/R
	40-160.03 (meas. large)	I	Y060609	43817	792748/R
Finger extension splint	40-163	I	Y060609	43817	792767/R
Frog splint	40-165	I	Y060609	43817	1393660/R
Pump for invalid ring	70-544	I	V0880	n.d.	700350/r
Pill box	FOR.TGYH.012 Pill box	I	V0899	n.d.	1472414/R
	FOR.TGYH.007 Pill box – 7 case small	I	V0899	n.d.	1472445/R
	FOR.TGYH.AJ07 Pill box – 7 case big	I	V0899	n.d.	1472447/R
	FOR.TGYH. 098 Pill box – 28 case	I	V0899	n.d.	1472450/R
	FOR.TGYH.029.2 Daily Pill Box	I	V0899	n.d.	1473449/R
	FOR.TGYH.031 Pill box rounded – 7 case	I	V0899	n.d.	1487175/R
Pouch arm sling cotton fabric with pulling and rings	40-153.01 (without case meas. small)	I	Y060699	43262	37968/R
	40-153.02 (without case meas. medium)	I	Y060699	43262	57680/R
	40-153.03 (without case meas. large)	I	Y060699	43262	57762/R
	40-153.04 (without case meas. extra-large)	I	Y060699	43262	57763/R
	40-153.05 (with case meas. small)	I	Y060699	43262	640387/R
	40-153.06 (with case meas. medium)	I	Y060699	43262	640407/R
	40-153.07 (with case meas. large)	I	Y060699	43262	640427/R
	40-153.08 (with case meas. extra-large)	I	Y060699	43262	640428/R
	40-155.01 (without case meas. small)	I	Y060699	43262	381366/R
	40-155.02 (without case meas. medium)	I	Y060699	43262	381368/R
	40-155.03 (without case meas. large)	I	Y060699	43262	381369/R
	40-155.04 (without case meas. extra-large)	I	Y060699	43262	381377/R
Reservoir bag	70-555-08 (with valve for adult)	I	R03020201	n.d.	44537/R
	70-555-09 (with valve pediatric)	I	R03020201	n.d.	64884/R
	70-555-10 (with valve infant)	I	R03020201	n.d.	64888/R
	70-555-11 (without valve adult)	I	R03020201	n.d.	76909/R
	70-555-12 (without valve pediatric)	I	R03020201	n.d.	76927/R
	70-555-13 (without valve infant)	I	R03020201	n.d.	76952/R
Cast shoe	40-20029	I	M03050299	n.d.	1225626/R
	40-20030	I	M03050299	n.d.	1225628/R
	40-20031	I	M03050299	n.d.	1225631/R



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	40-20032	I	M03050299	n.d.	1225634/R
	40-20033	I	M03050299	n.d.	1225636/R
	40-20034	I	M03050299	n.d.	1225638/R
	40-20035	I	M03050299	n.d.	1225639/R
	40-20036	I	M03050299	n.d.	1126332/R
	40-20037	I	M03050299	n.d.	1128153/R
	40-20038	I	M03050299	n.d.	1128154/R
	40-20039	I	M03050299	n.d.	1128169/R
	40-20040	I	M03050299	n.d.	1128170/R
	40-20041	I	M03050299	n.d.	1128171/R
	40-20042	I	M03050299	n.d.	1128172/R
	40-20043	I	M03050299	n.d.	1128173/R
	40-20044	I	M03050299	n.d.	1128174/R
	40-20045	I	M03050299	n.d.	1128176/R
	40-20046	I	M03050299	n.d.	1128177/R
	40-20047/48	I	M03050299	n.d.	1128178/R
Enema spare set of 3 pieces	FOR.005.004	I	U0899	n.d.	44348/R
Rubber inflation bulb	FOR.004.021 (with final valve and air manual opening valve)	I	Z12040180	42398	72533/R
	FOR.004.022 (with final valve)	I	Z12040180	42398	58352/R
Finger splint	40-170 (simple splint)	I	M030505	42050	58077/R
	40-172 (finger extension splint)	I	M030505	42050	77068/R
	40-175 (frog splint)	I	M030505	42050	77072/R
	40-175S (frog splint SMALL)	I	M030505	42050	1461430/R
	40-175M (frog splint MEDIUM)	I	M030505	42050	1461431/R
	40-175L (frog splint LARGE)	I	M030505	42050	1461432/R
Pill cutter	FOR.TGYH.002 Pill cutter	I	V0899	n.d.	1472542/R
	FOR.TGYH.005 Pill cutter	I	V0899	n.d.	1472552/R
Pill crusher & cutter	FOR.TGYH.LMY01	I	V0899	n.d.	1472536/R
Ankle binder	40-186-01 (meas. small)	I	Y061203	n.d.	1154686/R
	40-186-02 (meas. medium)	I	Y061203	n.d.	1154697/R
	40-186-03 (meas. large)	I	Y061203	n.d.	1154699/R
Tube for enema irrigator	FOR.005.002	I	U0899	n.d.	60980/R
Tube for oxygen for PVC resuscitator in case	70-555-07	I	R03020201	n.d.	64935/R
PVC tube in case	FOR.002.012 (100 cm)	I	R03010303	32202	1320019/R
	FOR.002.021 (150 cm)	I	R03010303	32202	1153011/R
	FOR.002.0122 (200 cm)	I	R03010303	32202	1320023/R
Polyethylene female urinal	FOR.001.012 (in polybag)	I	Y091299	34867	29880/R
	FOR.001.013 (in case)	I	Y091299	34867	1320745/R
Polyethylene male urinal	FOR.001.010 (in polybag)	I	A06030399	40504	29818/R
	FOR.001.010/T (with cap in polybag)	I	A06030399	40504	1320710/R
	FOR.001.011 (in case)	I	A06030399	40504	1320737/R
On-off valve for silicone rianimator	70-555-36	I	R03020201	n.d.	65022/R



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For this purpose FOR.ME.SA. srl guarantees and declares under his own responsibility as follows:

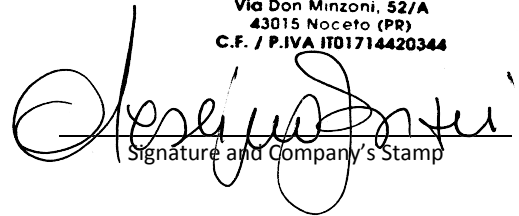
1. The Device shown on this document fulfil the regulatory essential requires to Annex I Directive 93/42/EEC;
2. The Device shown on this document belong to the Class I;
3. The Device shown on this document AREN'T MEASURING INSTRUMENTS;
4. The Device shown on this document AREN'T INTENDED FOR CLINICAL INVESTIGATIONS;
5. The Device shown on this document are readed in NOT STERILE package.

I also declare that company FOR.ME.SA. srl will keep at the disposal of Health Authorities documentation referred to Annex VII of Directive 93/42/EEC for **five years (or over the whole lifetime of Device)** starting last production date of Device.

2016, 14th november

Place and date of issue

FOR.ME.SA. srl
Via Don Minzoni, 52/A
43015 Noceto (PR)
C.F. / P.IVA IT01714420344


Signature and Company's Stamp