

**DICHIARAZIONE DI CONFORMITA' CE**  
**Ai sensi dell'Allegato VII della Direttiva 93/42/CEE e s.m.i.**



La scrivente ditta **FOR.ME.SA. SRL**, fabbricante dei Dispositivi Medici indicati nel presente documento, con sede in Via Canvelli 6, 43015 Noceto (PR) dichiara sotto la propria e unica responsabilità che i Dispositivi sotto elencati soddisfano i requisiti essenziali richiesti dall'Allegato I della Direttiva 93/42/CEE e s.m.i. .

DESCRIZIONE	CODICE	CLASSE	CND	GMDN	RDM	PARAF
<b>Aspiratore nasale</b> <i>Nasal aspirator</i>	<b>FOR.70-545</b>	I	V0299	n.d.	<b>36492/R</b>	<b>912101793</b>
<b>Banda biadesiva per il fissaggio dei cateteri esterni maschili</b>	<b>FOR.007.999</b>	I	U0780	n.d.	<b>29607/R</b>	<b>911124915</b>
<b>Banda biadesiva per il fissaggio dei cateteri esterni maschili</b>	<b>FOR.007.990</b>	I	U0780	n.d.	<b>915735/R</b>	<b>972760538</b>
<b>Borsa acqua calda</b>	<b>70-501.04</b> (bimbi)	I	V0401	12042	<b>57431/R</b>	<b>910327966</b>
	<b>70-501.40</b> (monolamellata Deluxe)	I	V0401	12042	<b>588987/R</b>	<b>922387776</b>
	<b>70-501.39</b> (bilamellata Deluxe)	I	V0401	12042	<b>589007/R</b>	<b>922387788</b>
	<b>70-501.10</b> (monolamellata Conventional)	I	V0401	12042	<b>1011877/R</b>	<b>901698896</b>
	<b>70-501.11</b> (bilamellata Conventional)	I	V0401	12042	<b>381383/R</b>	<b>901698946</b>
<b>70-501.06</b> (con cover)	I	V0401	12042	-		
<b>Borsa acqua calda in PVC</b>	<b>70-501.41</b>	I	V0401	12042	<b>1619810</b>	<b>973916570</b>
<b>Borsa ghiaccio</b>	<b>70-503.04</b> (ovale)	I	M9001	12082	<b>19907/R</b>	<b>912101348</b>
	<b>70-503.05</b> (cervicale)	I	M9001	12082	<b>19913/R</b>	<b>911465298</b>
	<b>70-503.01</b> (rotonda misura 20)	I	M9001	12082	<b>19903/R</b>	<b>911439267</b>
	<b>70-503.02</b> (rotonda misura 28)	I	M9001	12082	<b>44199/R</b>	<b>911439279</b>
	<b>70-503.03</b> (rotonda misura 25)	I	M9001	12082	<b>44203/R</b>	<b>911439281</b>
	<b>70-503.11</b> (TEAM blu mis. 25 in astuccio)	I	M9001	12082	<b>589048/R</b>	<b>922317805</b>
	<b>70-503.11/S</b> (TEAM blu mis. 25 in sacchetto)	I	M9001	12082	<b>1380121/R</b>	
	<b>70-503.12</b> (TEAM blu mis. 28 in astuccio)	I	M9001	12082	<b>589055/R</b>	<b>922317817</b>
	<b>70-503.12/S</b> (TEAM blu mis. 28 in sacchetto)	I	M9001	12082	<b>1380122/R</b>	
	<b>70-503.13</b> (TEAM blu mis. 31 in astuccio)	I	M9001	12082	<b>589050/R</b>	<b>922317829</b>
	<b>70-503.13/S</b> (TEAM blu mis. 31 in sacchetto)	I	M9001	12082	<b>1380123/R</b>	
<b>70-503.08</b> (AVANA mis. 25 in astuccio)	I	M9001	12082	<b>19947/R</b>		
<b>70-503.08/S</b> (AVANA mis.25 in sacchetto)	I	M9001	12082	-		



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Cod. Mecc.: PR 017790



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	<b>70-503.09</b> (AVANA mis. 28 in astuccio) <b>70-503.09/S</b> (AVANA mis.28 in sacchetto)	M9001   M9001	12082 12082	<b>44171/R</b> -			
	<b>70-503.10</b> (AVANA mis. 31 in astuccio) <b>70-503.10/S</b> (AVANA mis.31 in sacchetto)	M9001   M9001	12082 12082	<b>44176/R</b> -			
<b>Bracciale per sfigmomanometro</b>	<b>FOR.004.014</b> (con velcro e anello OBESI) <b>FOR.004.015</b> (con velcro e anello)	Z12040180   Z12040180	n.d. n.d.	<b>58453/R</b> <b>70613/R</b>	<b>922388448</b> <b>22388451</b>		
	<b>FOR.004.017</b> (con velcro e anello con camera d'aria inserita 1 via) <b>FOR.004.018</b> (con velcro e anello con camera d'aria inserita 2 vie)	Z12040180   Z12040180	n.d. n.d.	<b>70627/R</b> <b>71494/R</b>	<b>960789562</b> <b>922388424</b>		
	<b>FOR.004.019</b> (con velcro e anello con camera d'aria inserita 1 via per OBESI) <b>FOR.004.020</b> (con velcro e anello con camera d'aria inserita 2 vie per OBESI)	Z12040180   Z12040180	n.d. n.d.	<b>71518/R</b> <b>71520/R</b>	<b>939550719</b> <b>922388436</b>		
	<b>FOR.004.010</b> (adulti 1 via) <b>FOR.004.011</b> (adulti 2 vie)	Z12040180   Z12040180	34978 34978	<b>58395/R</b> <b>72554/R</b>	<b>910165240</b> <b>910165253</b>		
	<b>FOR.004.012</b> (pediatrica 1 via) <b>FOR.004.013</b> (pediatrica 2 vie)	Z12040180   Z12040180	34978 34978	<b>72560/R</b> <b>72564/R</b>	<b>911465300</b> <b>911465312</b>		
<b>Camera d'aria per sfigmomanometro</b>	<b>FOR.004.029</b> (obesi 1 via) <b>FOR.004.030</b> (obesi 2 vie)	Z12040180   Z12040180	34978 34978	<b>72585/R</b> <b>72591/</b>	<b>922388463</b> <b>922388475</b>		
	<b>Cannula anale</b>	<b>FOR.005.006</b>	U0899	n.d.	<b>91968/R</b> <b>911465336</b>		
<b>Cannula vaginale</b>	<b>FOR.005.005</b>	U0899	n.d.	<b>91938/R</b> <b>911465324</b>			
<b>Catetere esterno maschile in lattice</b>	<b>FOR.007.025</b> (diam. 25 mm) <b>FOR.007.030</b> (diam. 30 mm) <b>FOR.007.035</b> (diam. 35 mm)	U070201   U070201   U070201	34929 34929 34929	<b>29559/R</b> <b>38009/R</b> <b>38014/R</b>			
	<b>FOR.007.025</b> (diam. 25 mm) <b>FOR.007.030</b> (diam. 30 mm) <b>FOR.007.035</b> (diam. 35 mm)	U070201   U070201   U070201	34929 34929 34929	<b>884234/R</b> <b>884235/R</b> <b>884236/R</b>			
<b>Catetere esterno maschile in silicone</b>	<b>FOR.007.S25</b> (diam. 25 mm) <b>FOR.007.S30</b> (diam. 30 mm) <b>FOR.007.S35</b> (diam. 35 mm)	U070201   U070201   U070201	34929 34929 34929	<b>1368176/R</b> <b>1368177/R</b> <b>1368178/R</b>	<b>970431538</b> <b>970431540</b> <b>970431553</b>		
	<b>Cestello porta flebo</b>	<b>CESTELLOFL</b>	V0899	n.d.	<b>1564625/R</b> <b>922388614</b>		
	<b>Ciambella gonfiabile Conventional</b>	<b>70-507.01</b> (diam. 35 cm) <b>70-507.02</b> (diam. 40 cm) <b>70-507.03</b> (diam. 43 cm) <b>70-507.04</b> (diam. 45 cm)	V0803   V0803   V0803   V0803	41058 41058 41058 41058	<b>19960/R</b> <b>44231/R</b> <b>44289/R</b> <b>44328/R</b>	<b>912938646</b> <b>912938659</b> <b>912938661</b> <b>912938673</b>	
<b>Ciambella gonfiabile per invalidi in gomma rossa Team DELUXE c/pompa</b>		<b>70-506.01P</b> (diam.35 cm) <b>70-506.02P</b> (diam 40 cm) <b>70-506.04P</b> (diam 43 cm) <b>70-506.03P</b> (diam. 45 cm)	V0803   V0803   V0803   V0803	41058 41058 41058 41058	<b>1471907/R</b> <b>1471908/R</b> <b>1471909/R</b> <b>1471910/R</b>	<b>971607775</b> <b>971607787</b> <b>971607799</b> <b>971607801</b>	
		<b>Ciambella gonfiabile TEAM (Deluxe) s/pompa</b>	<b>70-508.01</b> (diam. 35 cm) <b>70-508.02</b> (diam. 40 cm) <b>70-508.03</b> (diam. 43 cm) <b>70-508.04</b> (diam. 45 cm)	V0803   V0803   V0803   V0803	41058 41058 41058 41058	<b>589030/R</b> <b>589031/R</b> <b>589033/R</b> <b>589034/R</b>	<b>922883804</b> <b>922883816</b> <b>922883828</b> <b>922883830</b>
			<b>Ciambella in poliuretano espanso</b>	<b>70-506.06</b> (a ferro di cavallo) <b>70-506.07</b> (rotonda)	V0803   V0803	41058 41058	<b>544727/R</b> <b>1024166/R</b>



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Collare cervicale morbido	40-135.01 (misura piccola)	I	Y060312	41039	36612/R	
	40-135.02 (misura media)	I	Y060312	41039	57562/R	
	40-132.03 (misura grande)	I	Y060312	41039	57574/R	
	40-132.04 (misura extra grande)	I	Y060312	41039	57584/R	
	40-135.05 (misura piccola) DFI UXF	I	Y060312	41039	1476259/R	
	40-135.06 (misura media) DFI UXF	I	Y060312	41039	1476260/R	
	40-135.07 (misura grande) DELUXE	I	Y060312	41039	1476261/R	
	40-135.08 (misura extra grande) DELUXE	I	Y060312	41039	1476262/R	
Collare cervicale rigido	40-142.01 (misura piccola)	I	Y060312	41039	36949/R	
	40-142.02 (misura media)	I	Y060312	41039	57600/R	
	40-142.03 (misura grande)	I	Y060312	41039	57603/R	
	40-142.04 (misura extra grande)	I	Y060312	41039	57613/R	
	40-142.13 (misura piccola) DELUXE	I	Y060312	41039	1476181/R	
	40-142.14 (misura media) DELUXE	I	Y060312	41039	1476187/R	
	40-142.15 (misura grande) DELUXE	I	Y060312	41039	1476194/R	
	40-142.16 (misura extra grande) DELUXE	I	Y060312	41039	1476196/R	
Collare cervicale semi rigido	40-138.01 (misura piccola)	I	Y060312	41039	381371/R	
	40-138.02 (misura media)	I	Y060312	41039	381372/R	
	40-138.03 (misura grande)	I	Y060312	41039	381373/R	
	40-138.04 (misura extra grande)	I	Y060312	41039	381375/R	
Collare cervicale "Philadelphia"	40-142.05 (misura piccola)	I	Y060312	41039	36966/R	912101488
	40-142.06 (misura media)	I	Y060312	41039	57656/R	912101502
	40-142.07 (misura grande)	I	Y060312	41039	57661/R	912101514
	40-142.08 (misura extra grande)	I	Y060312	41039	57665/R	912101526
Copri sacca urina utilizzabile con sacche urina con o senza scarico	39070	I	T030199	n.d.	1542875/R	972712576
Accessorio optional copri tubo per cod. 39070 copri sacca urina	39071	I	T030199	n.d.	1551151/R	972712638
Enteroclisma	FOR.005.001	I	U0899	32616	19964/R	908989837
Gelatina caldo-freddo	FOR.010.034 (14x18 cm in TNT)	I	M030504	37240	20470/R	
	FOR.010.034/A (14x18 cm in TNT in astuccio)	I	M030504	37240	1380159/R	
	FOR.010.047 (14x24 cm in busta chiusura in velcro)	I	M030504	37240	1247070/R	
	FOR.010.047/A (14x24 cm in busta con chiusura in velcro in astuccio)	I	M030504	37240	1380161/R	
Gelatina caldo-freddo in taffetà 12x25 cm	FOR.010.049	I	M030504	37240	1619773	973916568
Giotty (tritapillole elettrico)	FOR.GIOTTY	I	V0880	n.d.	1228538/R	960807889
Guanti in cotone per allergie dermatologiche	FOR.010.0106/0 (misura 6.0)	I	T0199	18039	427613/R	911145050
	FOR.010.0106/5 (misura 6.5)	I	T0199	18039	1026268/R	911145062
	FOR.010.0107/0 (misura 7.0)	I	T0199	18039	1026269/R	911145074
	FOR.010.0107/5 (misura 7.5)	I	T0199	18039	1026271/R	911145086
	FOR.010.0108/0 (misura 8.0)	I	T0199	18039	1026274/R	911145098
	FOR.010.0108/5 (misura 8.5)	I	T0199	18039	1026276/R	11145100
	FOR.010.0109/0 (misura 9.0)	I	T0199	18039	1026280/R	911145112
Immobilizzatore per spalla	40-150.01 (misura small)	I	Y060699	43262	381319/R	921456291
	40-150.02 (misura media)	I	Y060699	43262	381328/R	921456303
	40-150.03 (misura grande)	I	Y060699	43262	381330/R	921456315
Lenzuolino in cotone con anelli	FOR.011.09 (misura 50x70 cm)	I	T04010201	35339	1252338/R	926649245
	FOR.011.10 (misura 90x140 cm)	I	T04010201	35339	1252344/R	926649258
	FOR.011.11 (misura 130x140 cm)	I	T04010201	35339	1252345/R	926649260
	FOR.011.12 (misura 200x140 cm)	I	T04010201	35339	1252346/R	926649272
	FOR.011.13 (misura 230x140 cm)	I	T04010201	35339	1252347/R	926649284



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Lenzuolino in gomma con anelli	FOR.011.01 (misura 60x90 cm)	T04010201	35339	20002/R	911060440
	FOR.011.02 (misura 90x100 cm)	T04010201	35339	57478/R	11060453
	FOR.011.03 (misura 90x120 cm)	T04010201	35339	57490/R	911060465
	FOR.011.04 (misura 90x150 cm)	T04010201	35339	57498/R	911060477
	FOR.011.05 (misura 90x180 cm)	T04010201	35339	57522/R	911060489
	FOR.011.06 (misura 90x200 cm)	T04010201	35339	57530/R	911060491
	FOR.011.07 (misura 90x70 cm)	T04010201	35339	57466/R	912101312
	FOR.011.08 (misura 90x90 cm)	T04010201	35339	57474/R	912101324
Lenzuolino in cotone con elastici	FOR.011.14 (misura 50x70 cm)	V0880	35339	1421268/R	971179496
	FOR.011.15 (misura 90x140 cm)	V0880	35339	1421274/R	971179522
	FOR.011.16 (misura 130x140 cm)	V0880	35339	1421281/R	971179559
	FOR.011.17 (misura 200x140 cm)	V0880	35339	1421283/R	971179561
	FOR.011.18 (misura 230x140 cm)	V0880	35339	1421286/R	971179585
Mascherina gel face	FOR.010.101	V9099	n.d.	1039926/R	922387826
Mascherina gel per emicranie	FOR.010.099	V9099	n.d.	88293/R	912475845
Mascherina gel BEADS OCCHI	FOR.010.102	M030504	n.d.	1693032	975020595
Mascherina gel BEADS FACE	FOR.010.103	M030504	n.d.	1693290	975020607
Mascherina in plastica bianca per adulti	FOR.002.008	R03010301	n.d.	1153029/R	908454883
Maschera in silicone per pallone rianimazione	70-555-16 (misura 00)	R03020201	n.d.	64910/R	921900231
	70-555-17 (misura 0)	R03020201	n.d.	64799/R	921900243
	70-555-18 (misura 1)	R03020201	n.d.	64802/R	921900256
	70-555-19 (misura 2)	R03020201	n.d.	64804/R	921900268
	70-555-20 (misura 3)	R03020201	n.d.	64807/R	921900270
	70-555-21 (misura 4)	R03020201	n.d.	64808/R	921900282
	70-555-22 (misura 5)	R03020201	n.d.	64809/R	921900294
Mascherina monoculare protettiva	FOR.010.016	T0306	n.d.	1564069	902309448
Padella ammalati	FOR.001.009	Y091299	34867	28157/R	902308600
Pallone di rianimazione in silicone	70-555-01 (adulti con accessori)	R03020201	17591	20018/R	900036930
	70-555-02 (pediatrico con accessori)	R03020201	17591	57773/R	900036967
	70-555-03 (neonatale con accessori)	R03020201	17591	57780/R	900036981
	70-555-04 (adulti senza accessori)	R03020201	17591	76556/R	922388297
	70-555-05 (pediatrico senza accessori)	R03020201	17591	76570/R	922388311
	70-555-06 (neonatale senza accessori)	R03020201	17591	76598/R	922388309
	Polsiera con doppia chiusura in velcro	40-160.01 (misura piccola)	Y060609	43817	792727/R
40-160.02 (misura media)		Y060609	43817	792747/R	921564225
40-160.03 (misura grande)		Y060609	43817	792748/R	921564237
Polsiera con supporto per pollice	40-163	Y060609	43817	792767/R	912101589
Polsiera con stecca interna preformata	40-165	Y060609	43817	1393660/R	922387954
Pompa per ciambelle	70-544	V0880	n.d.	700350/r	900037108
Protezione per gesso monouso	FOR.FM-080 (da braccio)	Y090612	n.d.	1666130	
	FOR.FM-081 (da gamba)	Y090618	n.d.	1666137	
Protezione per gesso riutilizzabile	FOR.FS-2146 (da braccio)	Y090612	n.d.	1666093	
	FOR.FS-2148 (da gamba)	Y090618	n.d.	1666124	
Reggibraccio in cotone con tiranti e anello	40-153.01 (senza astuccio misura piccola)	Y060699	43262	37968/R	911458026
	40-153.02 (senza astuccio misura media)	Y060699	43262	57680/R	911458038
	40-153.03 (senza astuccio misura grande)	Y060699	43262	57762/R	911458040
	40-153.04 (senza astuccio misura extra grande)	Y060699	43262	57763/R	911458053



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	<b>40-153.05</b> (con astuccio misura piccola) <b>40-153.06</b> (con astuccio misura media) <b>40-153.07</b> (con astuccio misura grande) <b>40-153.08</b> (con astuccio misura extra grande)  <b>40-155.01</b> (senza astuccio misura piccola) <b>40-155.02</b> (senza astuccio misura media) <b>40-155.03</b> (senza astuccio misura grande) <b>40-155.04</b> (senza astuccio misura extra grande)	Y060699   Y060699   Y060699   Y060699    Y060699   Y060699   Y060699   Y060699	43262 43262 43262 43262  43262 43262 43262 43262	<b>640387/R</b> <b>640407/R</b> <b>640427/R</b> <b>640428/R</b>  <b>381366/R</b> <b>381368/R</b> <b>381369/R</b> <b>381377/R</b>	<b>970447684</b> <b>970447696</b> <b>970447722</b> <b>970447734</b>  <b>921456253</b> <b>921456265</b> <b>921456277</b> <b>921456289</b>
<b>Sacca reservoir per ossigeno per pallone rianimazione</b>	<b>70-555-08</b> (completo di valvola adulti) <b>70-555-09</b> (completo di valvola pediatrica) <b>70-555-10</b> (completo di valvola neonatale)  <b>70-555-11</b> (senza valvola adulti) <b>70-555-12</b> (senza valvola pediatrica) <b>70-555-13</b> (senza valvola neonatale)	R03020201   R03020201   R03020201    R03020201   R03020201   R03020201	n.d. n.d. n.d.  n.d. n.d. n.d.	<b>44537/R</b> <b>64884/R</b> <b>64888/R</b>  <b>76909/R</b> <b>76927/R</b> <b>76952/R</b>	<b>900389952</b> <b>900389976</b> <b>900389988</b>  <b>922388350</b> <b>922388362</b> <b>922388374</b>
<b>Sacca urina senza scarico (STD)</b>	<b>FOR.003.001</b> sacca urine 2000 cc tubo cm 90 standard sfuse <b>FOR.003.002</b> sacca urine 2000 cc tubo cm 90 standard in cf. da 10 pz <b>FOR.003.019</b> sacca urina 2000 cc tubo cm 90 standard in cf. da 30 pz <b>FOR.003.003</b> sacca urine 2000 cc tubo cm 130 standard sfuse <b>FOR.003.004</b> sacca urine 2000 cc tubo cm 130 standard in cf. da 10 pz <b>FOR.003.020</b> sacca urine 2000 cc tubo cm 130 standard in cf. da 30 pz	A06030301   A06030301   A06030301   A06030301   A06030301   A06030301	n.d. n.d. n.d. n.d. n.d.	<b>1244389/R</b>  <b>1244390/R</b> <b>1244392/R</b> <b>1244393/R</b> <b>1244394/R</b> <b>1244395/R</b>	<b>901447817</b>  <b>901447971</b> <b>911465375</b> <b>901447983</b> <b>901447995</b> <b>910836129</b>
<b>Sacca urina con scarico (NRV)</b>	<b>FOR.003.005</b> (nrv tubo 90 sfuse) <b>FOR.003.006</b> (nrv tubo 90 10 pz) <b>FOR.003.013</b> (nrv tubo 90 30 pz) <b>FOR.003.007</b> (nrv tubo 130 sfuse) <b>FOR.003.008</b> (nrv tubo 130 10 pz) <b>FOR.003.021</b> (nrv tubo 130 30 pz) <b>FOR.003.024</b> (nrv tubo 90 senza scarico)	A06030301   A06030301   A06030301   A06030301   A06030301   A06030301   A06030301	n.d. n.d. n.d. n.d. n.d. n.d. n.d.	- <b>1244391/R</b> <b>1317071/R</b> - <b>1244397/R</b> <b>1244396/R</b> <b>1386123/R</b>	<b>901448009</b> <b>902551845</b> <b>910836105</b> <b>901448011</b> <b>902551872</b> <b>910836117</b> <b>922387586</b>
<b>Sacca urina da gamba</b>	<b>FOR.003.009</b> sacca urine da gamba 750 cc tubo cm 10 in cf. da 10 pz con lacci e bottoni con fustella  <b>FOR.003.010</b> sacca urine da gamba 750 cc tubo cm 35 in cf. da 10 pz con lacci e bottoni con fustella  <b>FOR.003.022</b> sacca urine 750 cc. da gamba tubo cm. 10 c/valvola di non ritorno in cf.da 30 pz lacci e bottoni	A06030301    A06030301    A06030301	n.d.  n.d.  n.d.	<b>1386126/R</b>  <b>1386130/R</b>  <b>1386127/R</b>	<b>901448023</b>  <b>901448047</b>  <b>911041022</b>
<b>Scarpa coprighesso</b>	<b>40-20029</b> <b>40-20030</b> <b>40-20031</b> <b>40-20032</b> <b>40-20033</b> <b>40-20034</b> <b>40-20035</b> <b>40-20036</b> <b>40-20037</b>	M03050299   M03050299   M03050299   M03050299   M03050299   M03050299   M03050299   M03050299   M03050299	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	<b>1225626/R</b> <b>1225628/R</b> <b>1225631/R</b> <b>1225634/R</b> <b>1225636/R</b> <b>1225638/R</b> <b>1225639/R</b> <b>1126332/R</b> <b>1128153/R</b>	<b>926500796</b> <b>926500808</b> <b>926500810</b> <b>926500822</b> <b>926500834</b> <b>926500846</b> <b>926500859</b> <b>922387966</b> <b>922387978</b>



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	40-20038		M03050299	n.d.	1128154/R	922387980
	40-20039		M03050299	n.d.	1128169/R	922387992
	40-20040		M03050299	n.d.	1128170/R	922388006
	40-20041		M03050299	n.d.	1128171/R	922388018
	40-20042		M03050299	n.d.	1128172/R	922388020
	40-20043		M03050299	n.d.	1128173/R	922388032
	40-20044		M03050299	n.d.	1128174/R	922388044
	40-20045		M03050299	n.d.	1128176/R	922388057
	40-20046		M03050299	n.d.	1128177/R	922388069
	40-20047/48		M03050299	n.d.	1128178/R	922388071
<b>Serie 3 pezzi ricambi per enteroclisma</b>	<b>FOR.005.004</b>		U0899	n.d.	44348/R	901420935
<b>Soffieria per sfigmomanometro</b>	<b>FOR.004.021</b> (con valvola e rubinetto) <b>FOR.004.022</b> (con valvola)		Z12040180 Z12040180	42398 42398	72533/R 58352/R	939550669 902308598
<b>Splint per dita in plastica mis. 1</b>	<b>40-251-1</b>		M030505	n.d.	1614447	973733520
<b>Splint per dita in plastica mis. 2</b>	<b>40-251-2</b>		M030505	n.d.	1614397	973733532
<b>Splint per dita in plastica mis. 3</b>	<b>40-251-3</b>		M030505	n.d.	1614448	973733544
<b>Splint per dita in plastica mis. 4</b>	<b>40-251-4</b>		M030505	n.d.	1614449	973733557
<b>Splint per dita in plastica mis. 5</b>	<b>40-251-5</b>		M030505	n.d.	1614450	973733569
<b>Splint per dita in plastica mis. 5,5</b>	<b>40-251-55</b>		M030505	n.d.	1614451	973733571
<b>Splint per dita in plastica mis. 6</b>	<b>40-251-6</b>		M030505	n.d.	1614452	973733583
<b>Splint per dita in plastica mis. 7</b>	<b>40-251-7</b>		M030505	n.d.	1614453	973733595
<b>Stecche per frattura dita mis. S</b>	<b>40-252-S</b>		M030505	n.d.	1614469	
<b>Stecche per frattura dita mis. M</b>	<b>40-252-M</b>		M030505	n.d.	1614471	
<b>Stecche per frattura dita mis. L</b>	<b>40-252-L</b>		M030505	n.d.	1614472	
<b>Stecca per dita</b>	<b>40-170</b> (semplice)		M030505	42050	58077/R	912101591
	<b>40-172</b> (adattabile con estensione)		M030505	42050	77068/R	939550339
	<b>40-175</b> (a rana adattabile universale)		M030505	42050	77072/R	
	<b>40-175S</b> (a rana misura SMALL)		M030505	42050	1461430/R	971477029
	<b>40-175M</b> (a rana misura MEDIUM)		M030505	42050	1461431/R	971477031
	<b>40-175L</b> (a rana misura LARGE)		M030505	42050	1461432/R	971477043
<b>Stecca per dita semplice deluxe</b>	<b>40-170-DS</b> (misura S)		M030505	n.d.	1515399/R	972063109
	<b>40-170-DM</b> (misura M)		M030505	n.d.	1515396/R	972063111
	<b>40-170-DL</b> (misura L)		M030505	n.d.	1510224/R	972063123
<b>Tallonette in silicone</b>	<b>40-186-01</b> (mis. Piccola)		Y061203	n.d.	1154686/R	921186894
	<b>40-186-02</b> (mis. Media)		Y061203	n.d.	1154697/R	921186906
	<b>40-186-03</b> (mis. Grande)		Y061203	n.d.	1154699/R	970434650
<b>Tubo per enteroclisma</b>	<b>FOR.005.002</b>		U0899	n.d.	60980/R	922387725
<b>Tubo per ossigeno per pallone di rianimazione in PVC medicale</b>	<b>70-555-07</b>		R03020201	n.d.	64935/R	939550430
<b>Tubo raccordato in PVC medicale</b>	<b>FOR.002.012</b> (100 cm)		R03010303	32202	1320019/R	906789401
	<b>FOR.002.021</b> (150 cm)		R03010303	32202	1153011/R	923305801
	<b>FOR.002.0122</b> (200 cm)		R03010303	32202	1320023/R	923305813
<b>Urinale donna</b>	<b>FOR.001.012</b> (in sacchetto)		Y091299	34867	29880/R	902308651
	<b>FOR.001.013</b> (in astuccio)		Y091299	34867	1320745/R	
<b>Urinale donna con tappo</b>	<b>FOR.001.012/T</b> (in sacchetto)		Y091299	34867	1620175/R	973916556
<b>Urinale uomo</b>	<b>FOR.001.010</b> (in sacchetto)		A06030399	40504	29818/R	902308636
	<b>FOR.001.010/T</b> (con tappo in sacchetto)		A06030399	40504	1320710/R	922387574
	<b>FOR.001.011</b> (in astuccio)		A06030399	40504	1320737/R	
<b>Valvola on-off per pallone rianimazione</b>	<b>70-555-36</b>		R03020201	n.d.	65022/R	923305825

A tale scopo la scrivente garantisce e dichiara sotto la propria responsabilità quanto segue:

1. I dispositivi indicati nel presente documento soddisfano tutti i requisiti essenziali applicabili, previsti dall'Allegato I della Direttiva 93/42/CE concernente i dispositivi medici e alle norme applicabili;
2. I Dispositivi medici in oggetto devono considerarsi inclusi nella **classe I** ai sensi della **Regola 1** dell'**Allegato IX** della Direttiva 93/42/CEE;
3. I dispositivi indicati nel presente documento **NON SONO STRUMENTI DI MISURA.**
4. I dispositivi indicati nel presente documento **NON SONO DESTINATI A INDAGINI CLINICHE.**
5. I dispositivi indicati nel presente documento vengono commercializzati in confezione **NON STERILE.**
6. Che **NON E' CONSENTITO** utilizzare/installare i Dispositivi in oggetto al di fuori della destinazione d'uso prevista dalla FOR.ME.SA S.r.l.
7. Che verrà tenuto a disposizione delle Autorità Competenti la documentazione comprovante la conformità alla Direttiva 93/42/CEE per cinque (5) anni a partire dall'ultima data di produzione del Dispositivo in oggetto

Si dichiara infine che la ditta For.me.sa. srl si impegna a conservare e a mettere a disposizione delle Autorità competenti la documentazione tecnica specificata nell'Allegato II della Direttiva 93/42/CEE, per un periodo di 10 anni dalla data di ultima fabbricazione del prodotto.

**04 GIUGNO 2018**

Luogo e data di emissione

**FOR.ME.SA. SRL**  
Via F.lli Canvelli, 6  
43015 NOCETO (PR)  
COD.FISC. / P.IVA IT01714420344

BIZZI DESOLINA  
Firma e Timbro



## 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 Canvelli 6, 43015 Noceto (PR)

#### DECLARES

Under our responsibility that the following Devices satisfy Essential Requirements required from Annex I Directive 93/42/EEC:

DESCRIPTION	CODE	CLASS	CND	GMDN	RDM	PARAF
Nasal aspirator	FOR.70-545	I	V0299	n.d.	36492/R	912101793
Foam biadhesive strip for fixing the external male catheters	FOR.007.999	I	U0780	n.d.	29607/R	911124915
Foam biadhesive strip for fixing the external male catheters	FOR.007.990	I	U0780	n.d.	915735/R	972760538
Hot bag	70-501.04 (kids)	I	V0401	12042	57431/R	910327966
	70-501.40 (one-side ribbed Deluxe)	I	V0401	12042	588987/R	922387776
	70-501.39 (two-side ribbed Deluxe)	I	V0401	12042	589007/R	922387788
	70-501.10 (one-side Conventional)	I	V0401	12042	1011877/R	901698896
	70-501.11 (two-side Conventional)	I	V0401	12042	381383/R	901698946
70-501.06 (with cover)	I	V0401	12042	-		
PVC hot bag	70-501.41	I	V0401	12042	1619810	973916570
Ice bag	70-503.04 (oval)	I	M9001	12082	19907/R	912101348
	70-503.05 (cervical)	I	M9001	12082	19913/R	911465298
	70-503.01 (round size 20)	I	M9001	12082	19903/R	911439267
	70-503.02 (round size25)	I	M9001	12082	44199/R	911439279
	70-503.03 (round size 28)	I	M9001	12082	44203/R	911439281
	70-503.11 (TEAM blu mis. 25 in case)	I	M9001	12082	589048/R	922317805
	70-503.11/S (TEAM blu mis. 25 in polybag)	I	M9001	12082	1380121/R	
	70-503.12 (TEAM blu mis. 28 in case)	I	M9001	12082	589055/R	922317817
	70-503.12/S (TEAM blu mis. 28 in polybag)	I	M9001	12082	1380122/R	
	70-503.13 (TEAM blu mis. 31 in polybag)	I	M9001	12082	589050/R	922317829
70-503.13/S (TEAM blu mis. 31 in polybag)	I	M9001	12082	1380123/R		
70-503.08 (AVANA mis. 25 in polybag)	I	M9001	12082	19947/R		





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UNI CEI EN ISO 13485:2012

	<b>70-503.08/S</b> (AVANA mis.25 in polybag)		M9001	12082	-	
	<b>70-503.09</b> (AVANA mis. 28 in case)		M9001	12082	<b>44171/R</b>	
	<b>70-503.09/S</b> (AVANA mis.28 in polybag)		M9001	12082	-	
	<b>70-503.10</b> (AVANA mis. 31 in case)		M9001	12082	<b>44176/R</b>	
	<b>70-503.10/S</b> (AVANA mis.31 in polybag)		M9001	12082	-	
<b>Fabric cuff for sphygmomanometer</b>	<b>FOR.004.014</b> (fabric cuff with velcro and ring)		Z12040180	n.d.	<b>58453/R</b>	<b>922388448</b>
	<b>FOR.004.015</b> (with velcro and ring)		Z12040180	n.d.	<b>70613/R</b>	<b>22388451</b>
	<b>FOR.004.017</b> (inflatable cuff with velcro and ring 1 way)		Z12040180	n.d.	<b>70627/R</b>	<b>960789562</b>
	<b>FOR.004.018</b> (inflatable cuff with velcro and ring 2 ways)		Z12040180	n.d.	<b>71494/R</b>	<b>922388424</b>
	<b>FOR.004.019</b> (inflatable cuff for obese people with velcro and ring 1 way)		Z12040180	n.d.	<b>71518/R</b>	<b>939550719</b>
	<b>FOR.004.020</b> (inflatable cuff for obese people with velcro and ring 2 ways)		Z12040180	n.d.	<b>71520/R</b>	<b>922388436</b>
<b>Spare parts for sphygmomanometer</b>	<b>FOR.004.010</b> (adult 1 way)		Z12040180	34978	<b>58395/R</b>	<b>910165240</b>
	<b>FOR.004.011</b> (adult 2 ways)		Z12040180	34978	<b>72554/R</b>	<b>910165253</b>
	<b>FOR.004.012</b> (pediatric 1 way)		Z12040180	34978	<b>72560/R</b>	<b>911465300</b>
	<b>FOR.004.013</b> (pediatric 2 ways)		Z12040180	34978	<b>72564/R</b>	<b>911465312</b>
	<b>FOR.004.029</b> (obese 1 way)		Z12040180	34978	<b>72585/R</b>	<b>922388463</b>
	<b>FOR.004.030</b> (obese 2 ways)		Z12040180	34978	<b>72591/</b>	<b>922388475</b>
<b>Anal cannula</b>	<b>FOR.005.006</b>		U0899	n.d.	<b>91968/R</b>	<b>911465336</b>
<b>Vaginal cannula</b>	<b>FOR.005.005</b>		U0899	n.d.	<b>91938/R</b>	<b>911465324</b>
<b>External latex catheters in polybag</b>	<b>FOR.007.025</b> (diam. 25 mm)		U070201	34929	<b>29559/R</b>	
	<b>FOR.007.030</b> (diam. 30 mm)		U070201	34929	<b>38009/R</b>	
	<b>FOR.007.035</b> (diam. 35 mm)		U070201	34929	<b>38014/R</b>	
	<b>FOR.007.025</b> (diam. 25 mm)		U070201	34929	<b>884234/R</b>	
	<b>FOR.007.030</b> (diam. 30 mm)		U070201	34929	<b>884235/R</b>	
	<b>FOR.007.035</b> (diam. 35 mm)		U070201	34929	<b>884236/R</b>	
<b>External silicone catheters</b>	<b>FOR.007.S25</b> (diam. 25 mm)		U070201	34929	<b>1368176/R</b>	<b>970431538</b>
	<b>FOR.007.S30</b> (diam. 30 mm)		U070201	34929	<b>1368177/R</b>	<b>970431540</b>
	<b>FOR.007.S35</b> (diam. 35 mm)		U070201	34929	<b>1368178/R</b>	<b>970431553</b>
<b>Holder for bottle with physiological solution</b>	<b>CESTELLOFL</b>		V0899	n.d.	<b>1564625/R</b>	<b>922388614</b>
<b>Invalid ring - CONVENTIONAL</b>	<b>70-507.01</b> (diam. 35 cm)		V0803	41058	<b>19960/R</b>	<b>912938646</b>
	<b>70-507.02</b> (diam. 40 cm)		V0803	41058	<b>44231/R</b>	<b>912938659</b>
	<b>70-507.03</b> (diam. 43 cm)		V0803	41058	<b>44289/R</b>	<b>912938661</b>
	<b>70-507.04</b> (diam. 45 cm)		V0803	41058	<b>44328/R</b>	<b>912938673</b>
<b>Invalid ring with inflator inserted (DELUXE) with pump</b>	<b>70-506.01P</b> (diam.35 cm)		V0803	41058	<b>1471907/R</b>	<b>971607775</b>
	<b>70-506.02P</b> (diam 40 cm)		V0803	41058	<b>1471908/R</b>	<b>971607787</b>
	<b>70-506.04P</b> (diam 43 cm)		V0803	41058	<b>1471909/R</b>	<b>971607799</b>
	<b>70-506.03P</b> (diam. 45 cm)		V0803	41058	<b>1471910/R</b>	<b>971607801</b>
<b>Invalid ring - TEAM (DELUXE) without pump</b>	<b>70-508.01</b> (diam. 35 cm)		V0803	41058	<b>589030/R</b>	<b>922883804</b>
	<b>70-508.02</b> (diam. 40 cm)		V0803	41058	<b>589031/R</b>	<b>922883816</b>
	<b>70-508.03</b> (diam. 43 cm)		V0803	41058	<b>589033/R</b>	<b>922883828</b>



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	<b>70-508.04</b> (diam. 45 cm)		V0803	41058	<b>589034/R</b>	<b>922883830</b>
<b>Polyurethane foam pad</b>	<b>70-506.06</b> (horseshoe)		V0803	41058	<b>544727/R</b>	<b>912101375</b>
	<b>70-506.07</b> (round)		V0803	41058	<b>1024166/R</b>	<b>912101387</b>
<b>Soft cervical collar</b>	<b>40-135.01</b> (small size)		Y060312	41039	<b>36612/R</b>	
	<b>40-135.02</b> (medium size)		Y060312	41039	<b>57562/R</b>	
	<b>40-132.03</b> (large size)		Y060312	41039	<b>57574/R</b>	
	<b>40-132.04</b> (size extra-large)		Y060312	41039	<b>57584/R</b>	
	<b>40-135.05</b> (small size) DELUXE		Y060312	41039	<b>1476259/R</b>	
	<b>40-135.06</b> (small size) DELUXE		Y060312	41039	<b>1476260/R</b>	
	<b>40-135.07</b> (small size) DELUXE		Y060312	41039	<b>1476261/R</b>	
	<b>40-135.08</b> (small size) DELUXE		Y060312	41039	<b>1476262/R</b>	
<b>Rigid cervical collar</b>	<b>40-142.01</b> (small size)		Y060312	41039	<b>36949/R</b>	
	<b>40-142.02</b> (medium size)		Y060312	41039	<b>57600/R</b>	
	<b>40-142.03</b> (large size)		Y060312	41039	<b>57603/R</b>	
	<b>40-142.04</b> (extra-large size)		Y060312	41039	<b>57613/R</b>	
	<b>40-142.13</b> (small size)		Y060312	41039	<b>1476181/R</b>	
	<b>40-142.14</b> (medium size)		Y060312	41039	<b>1476187/R</b>	
	<b>40-142.15</b> (large size)		Y060312	41039	<b>1476194/R</b>	
	<b>40-142.16</b> (extra-large size)		Y060312	41039	<b>1476196/R</b>	
<b>Semirigid cervical collar</b>	<b>40-138.01</b> (small size)		Y060312	41039	<b>381371/R</b>	
	<b>40-138.02</b> (medium size)		Y060312	41039	<b>381372/R</b>	
	<b>40-138.03</b> (large size)		Y060312	41039	<b>381373/R</b>	
	<b>40-138.04</b> (extra-large size)		Y060312	41039	<b>381375/R</b>	
<b>Cervical collar "Philadelphia"</b>	<b>40-142.05</b> (small size)		Y060312	41039	<b>36966/R</b>	<b>912101488</b>
	<b>40-142.06</b> (medium size)		Y060312	41039	<b>57656/R</b>	<b>912101502</b>
	<b>40-142.07</b> (large size)		Y060312	41039	<b>57661/R</b>	<b>912101514</b>
	<b>40-142.08</b> (extra-large size)		Y060312	41039	<b>57665/R</b>	<b>912101526</b>
<b>Bag Cover consistent with urinary bag with or without drainage valve</b>	<b>39070</b>		T030199	n.d.	<b>1542875/R</b>	<b>972712576</b>
<b>Optional component Pipe Cover for bag cover</b>	<b>39071</b>		T030199	n.d.	<b>1551151/R</b>	<b>972712638</b>
<b>Enema irrigator</b>	<b>FOR.005.001</b>		U0899	32616	<b>19964/R</b>	<b>908989837</b>
<b>Hot-cold gel</b>	<b>FOR.010.034</b> (14x18 cm in TNT)		M030504	37240	<b>20470/R</b>	
	<b>FOR.010.034/A</b> (14x18 cm in TNT in case)		M030504	37240	<b>1380159/R</b>	
	<b>FOR.010.047</b> (14x24 cm with velcro)		M030504	37240	<b>1247070/R</b>	
	<b>FOR.010.047/A</b> (14x24 cm with velcro in case)		M030504	37240	<b>1380161/R</b>	
<b>Hot-cold gel in taffetà 12x25 cm</b>	<b>FOR.010.049</b>		M030504	37240	<b>1619773</b>	<b>973916568</b>
<b>Giotty</b>	<b>FOR.GIOTTY</b>		V0880	n.d.	<b>1228538/R</b>	<b>960807889</b>
<b>Cotton gloves for skin allergies</b>	<b>FOR.010.0106/0</b> (misura 6.0)		T0199	18039	<b>427613/R</b>	<b>911145050</b>
	<b>FOR.010.0106/5</b> (misura 6.5)		T0199	18039	<b>1026268/R</b>	<b>911145062</b>
	<b>FOR.010.0107/0</b> (misura 7.0)		T0199	18039	<b>1026269/R</b>	<b>911145074</b>
	<b>FOR.010.0107/5</b> (misura 7.5)		T0199	18039	<b>1026271/R</b>	<b>911145086</b>
	<b>FOR.010.0108/0</b> (misura 8.0)		T0199	18039	<b>1026274/R</b>	<b>911145098</b>
	<b>FOR.010.0108/5</b> (misura 8.5)		T0199	18039	<b>1026276/R</b>	<b>11145100</b>
	<b>FOR.010.0109/0</b> (misura 9.0)		T0199	18039	<b>1026280/R</b>	<b>911145112</b>
<b>Shoulder immobilizer</b>	<b>40-150.01</b> (small size)		Y060699	43262	<b>381319/R</b>	<b>921456291</b>
	<b>40-150.02</b> (medium size)		Y060699	43262	<b>381328/R</b>	<b>921456303</b>
	<b>40-150.03</b> (large size)		Y060699	43262	<b>381330/R</b>	<b>921456315</b>
<b>Cotton sheet with rings</b>	<b>FOR.011.09</b> (measure 50x70 cm)		T04010201	35339	<b>1252338/R</b>	<b>926649245</b>
	<b>FOR.011.10</b> (measure 90x140 cm)		T04010201	35339	<b>1252344/R</b>	<b>926649258</b>



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	FOR.011.11 (measure 130x140 cm)		T04010201	35339	1252345/R	926649260
	FOR.011.12 (measure 200x140 cm)		T04010201	35339	1252346/R	926649272
	FOR.011.13 (measure 230x140 cm)		T04010201	35339	1252347/R	926649284
Rubber sheet with rings	FOR.011.01 (measure 60x90 cm)		T04010201	35339	20002/R	911060440
	FOR.011.02 (measure 90x100 cm)		T04010201	35339	57478/R	11060453
	FOR.011.03 (measure 90x120 cm)		T04010201	35339	57490/R	911060465
	FOR.011.04 (measure 90x150 cm)		T04010201	35339	57498/R	911060477
	FOR.011.05 (measure 90x180 cm)		T04010201	35339	57522/R	911060489
	FOR.011.06 (measure 90x200 cm)		T04010201	35339	57530/R	911060491
	FOR.011.07 (measure 90x70 cm)		T04010201	35339	57466/R	912101312
	FOR.011.08 (measure 90x90 cm)		T04010201	35339	57474/R	912101324
Cotton sheet with elastics	FOR.011.14 (measure 50x70 cm)		V0880	35339	1421268/R	971179496
	FOR.011.15 (measure 90x140 cm)		V0880	35339	1421274/R	971179522
	FOR.011.16 (measure 130x140 cm)		V0880	35339	1421281/R	971179559
	FOR.011.17 (measure 200x140 cm)		V0880	35339	1421283/R	971179561
	FOR.011.18 (measure 230x140 cm)		V0880	35339	1421286/R	971179585
Gel face mask	FOR.010.101		V9099	n.d.	1039926/R	922387826
Gel eyes mask for headache	FOR.010.099		V9099	n.d.	88293/R	912475845
Gel eyes mask BEADS	FOR.010.102		M030504	n.d.	1693032	975020595
Gel face mask BEADS	FOR.010.103		M030504	n.d.	1693290	975020607
White plastic mask for adults in case	FOR.002.008		R03010301	n.d.	1153029/R	908454883
Silicone mask for resuscitator	70-555-16 (size 00)		R03020201	n.d.	64910/R	921900231
	70-555-17 (size 0)		R03020201	n.d.	64799/R	921900243
	70-555-18 (size 1)		R03020201	n.d.	64802/R	921900256
	70-555-19 (size 2)		R03020201	n.d.	64804/R	921900268
	70-555-20 (size 3)		R03020201	n.d.	64807/R	921900270
	70-555-21 (size 4)		R03020201	n.d.	64808/R	921900282
	70-555-22 (size 5)		R03020201	n.d.	64809/R	921900294
Monocular mask	FOR.010.016		T0306	n.d.	1564069	902309448
Bed pan	FOR.001.009		Y091299	34867	28157/R	902308600
Silicone resuscitator	70-555-01 (adult with accessories)		R03020201	17591	20018/R	900036930
	70-555-02 (pediatric with accessories)		R03020201	17591	57773/R	900036967
	70-555-03 (infant with accessories)		R03020201	17591	57780/R	900036981
	70-555-04 (adult without accessories)		R03020201	17591	76556/R	922388297
	70-555-05 (pediatric without accessories)		R03020201	17591	76570/R	922388311
	70-555-06 (infant without accessories)		R03020201	17591	76598/R	922388309
Finger cot	40-160.01 (small size)		Y060609	43817	792727/R	921564213
	40-160.02 (medium size)		Y060609	43817	792747/R	921564225
	40-160.03 (large size)		Y060609	43817	792748/R	921564237
Finger extension splint	40-163		Y060609	43817	792767/R	912101589
Wristband with pre-formed internal splint	40-165		Y060609	43817	1393660/R	922387954
Pump for invalid ring	70-544		V0880	n.d.	700350/r	900037108
Disposable cast protector	FOR.FM-080 (for arm)		Y090612	n.d.	1666130	
	FOR.FM-081 (for leg)		Y090618	n.d.	1666137	
Reusable cast protector	FOR.FS-2146 (for arm)		Y090612	n.d.	1666093	
	FOR.FS-2148 (for leg)		Y090618	n.d.	1666124	
Pouch arm sling cotton fabric with pulling and rings	40-153.01 (without case small size)		Y060699	43262	37968/R	911458026
	40-153.02 (without case medium size)		Y060699	43262	57680/R	911458038



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	40-153.03 (without case large size)	I	Y060699	43262	57762/R	911458040
	40-153.04 (without case extra-large size)	I	Y060699	43262	57763/R	911458053
	40-153.05 (in case small size)	I	Y060699	43262	640387/R	970447684
	40-153.06 (in case medium size)	I	Y060699	43262	640407/R	970447696
	40-153.07 (in case large size)	I	Y060699	43262	640427/R	970447722
	40-153.08 (in case extra-large size)	I	Y060699	43262	640428/R	970447734
	40-155.01 (without case small size)	I	Y060699	43262	381366/R	921456253
	40-155.02 (without case medium size)	I	Y060699	43262	381368/R	921456265
	40-155.03 (without case large size)	I	Y060699	43262	381369/R	921456277
	40-155.04 (without case extra-large size)	I	Y060699	43262	381377/R	921456289
Reservoir Bag	70-555-08 (with valve for adult)	I	R03020201	n.d.	44537/R	900389952
	70-555-09 (pediatric with valve)	I	R03020201	n.d.	64884/R	900389976
	70-555-10 (infant with valve)	I	R03020201	n.d.	64888/R	900389988
	70-555-11 (without valve for adult)	I	R03020201	n.d.	76909/R	922388350
	70-555-12 (pediatric without valve)	I	R03020201	n.d.	76927/R	922388362
	70-555-13 (infant without valve)	I	R03020201	n.d.	76952/R	922388374
Urinary reservoir Bag without flush valve (STD)	FOR.003.001 urinary bag 2000 cc tube cm 90 standard in bulk provided	I	A06030301		1244389/R	901447817
	FOR.003.002 urinary bag 2000 cc tube cm 90 standard in box 10 pcs	I	A06030301	n.d.	1244390/R	901447971
	FOR.003.019 urinary bag 2000 cc tube cm 90 standard in bulk provided 30 pcs	I	A06030301	n.d.	1244392/R	911465375
	FOR.003.003 urinary bag 2000 cc tube cm 130 standard in bulk provided	I	A06030301	n.d.	1244393/R	901447983
	FOR.003.004 urinary bag 2000 cc tube cm 130 standard in box 10 pcs	I	A06030301	n.d.	1244394/R	901447995
	FOR.003.020 urinary bag 2000 cc tube cm 130 standard in box 30 pcs	I	A06030301	n.d.	1244395/R	910836129
Urinary reservoir Bag with flush valve (NRV)	FOR.003.005 (nrv tube 90 in bulk )	I	A06030301	n.d.	-	901448009
	FOR.003.006 (nrv tube 90 10 pcs)	I	A06030301	n.d.	1244391/R	902551845
	FOR.003.013 (nrv tube 90 30 pcs)	I	A06030301	n.d.	1317071/R	910836105
	FOR.003.007 (nrv tube 130 in bulk)	I	A06030301	n.d.	-	901448011
	FOR.003.008 (nrv tube 130 10 pcs)	I	A06030301	n.d.	1244397/R	902551872
	FOR.003.021 (nrv tube 130 30 pcs)	I	A06030301	n.d.	1244396/R	910836117
	FOR.003.024 (nrv tube 90 without discharge)	I	A06030301	n.d.	1386123/R	922387586
Urinary Leg Bag	FOR.003.009 urinary leg bag 750 cc tube cm 10 in box 10 pcs with strings and buttons	I	A06030301	n.d.	1386126/R	901448023
	FOR.003.010 urinary leg bag 750 cc tube cm 35 in box 10 pcs with strings and buttons	I	A06030301	n.d.	1386130/R	901448047
	FOR.003.022 urinary leg bag 750 cc. tube cm. 10 with flush valve box 30 pcs strings and buttons	I	A06030301	n.d.	1386127/R	911041022
Cast Shoe	40-20029	I	M03050299	n.d.	1225626/R	926500796
	40-20030	I	M03050299	n.d.	1225628/R	926500808
	40-20031	I	M03050299	n.d.	1225631/R	926500810
	40-20032	I	M03050299	n.d.	1225634/R	926500822
	40-20033	I	M03050299	n.d.	1225636/R	926500834
	40-20034	I	M03050299	n.d.	1225638/R	926500846
	40-20035	I	M03050299	n.d.	1225639/R	926500859



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	40-20036		M03050299	n.d.	1126332/R	922387966
	40-20037		M03050299	n.d.	1128153/R	922387978
	40-20038		M03050299	n.d.	1128154/R	922387980
	40-20039		M03050299	n.d.	1128169/R	922387992
	40-20040		M03050299	n.d.	1128170/R	922388006
	40-20041		M03050299	n.d.	1128171/R	922388018
	40-20042		M03050299	n.d.	1128172/R	922388020
	40-20043		M03050299	n.d.	1128173/R	922388032
	40-20044		M03050299	n.d.	1128174/R	922388044
	40-20045		M03050299	n.d.	1128176/R	922388057
	40-20046		M03050299	n.d.	1128177/R	922388069
	40-20047/48		M03050299	n.d.	1128178/R	922388071
Enema spare set of 3 pieces	FOR.005.004		U0899	n.d.	44348/R	901420935
Rubber inflation bulb	FOR.004.021 (with valve and faucet) FOR.004.022 (with valve)		Z12040180 Z12040180	42398 42398	72533/R 58352/R	939550669 902308598
Plastic splint for finger mis. 1	40-251-1		M030505	n.d.	1614447	973733520
Plastic splint for finger mis. 2	40-251-2		M030505	n.d.	1614397	973733532
Plastic splint for finger mis. 3	40-251-3		M030505	n.d.	1614448	973733544
Plastic splint for finger mis. 4	40-251-4		M030505	n.d.	1614449	973733557
Plastic splint for finger mis. 5	40-251-5		M030505	n.d.	1614450	973733569
Plastic splint for finger mis. 5,5	40-251-55		M030505	n.d.	1614451	973733571
Plastic splint for finger mis. 6	40-251-6		M030505	n.d.	1614452	973733583
Plastic splint for finger mis. 7	40-251-7		M030505	n.d.	1614453	973733595
Splint for finger fracture mis. S	40-252-S		M030505	n.d.	1614469	
Splint for finger fracture mis. M	40-252-M		M030505	n.d.	1614471	
Splint for finger fracture mis. L	40-252-L		M030505	n.d.	1614472	
Finger splint	40-170 (simple) 40-172 (adjustable) 40-175 (adjustable frog type) 40-175S (frog type size SMALL) 40-175M (frog type size MEDIUM) 40-175L (frog type size LARGE)		M030505 M030505 M030505 M030505 M030505 M030505	42050 42050 42050 42050 42050 42050	58077/R 77068/R 77072/R 1461430/R 1461431/R 1461432/R	912101591 939550339 971477029 971477031 971477043
Finger splint deluxe	40-170-DS (size small) 40-170-DM (size medium) 40-170-DL (size large)		M030505 M030505 M030505	n.d. n.d. n.d.	1515399/R 1515396/R 1510224/R	972063109 972063111 972063123
Silicon Heels	40-186-01 (size small) 40-186-02 (size medium) 40-186-03 (size large)		Y061203 Y061203 Y061203	n.d. n.d. n.d.	1154686/R 1154697/R 1154699/R	921186894 921186906 970434650
Tube for Enema Irrigator	FOR.005.002		U0899	n.d.	60980/R	922387725
Tube for Oxygen in case for PVC resuscitator	70-555-07		R03020201	n.d.	64935/R	939550430
Fitting PVC Tube	FOR.002.012 (100 cm) FOR.002.021 (150 cm) FOR.002.0122 (200 cm)		R03010303 R03010303 R03010303	32202 32202 32202	1320019/R 1153011/R 1320023/R	906789401 923305801 923305813
Female Urinal	FOR.001.012 (in polybag) FOR.001.013 (in case)		Y091299 Y091299	34867 34867	29880/R 1320745/R	902308651
Female Urinal with cap	FOR.001.012/T (in polybag)		Y091299	34867	1620175/R	973916556
Male Urinal	FOR.001.010 (in polybag) FOR.001.010/T (with cap in polybag) FOR.001.011 (in case)		A06030399 A06030399 A06030399	40504 40504 40504	29818/R 1320710/R 1320737/R	902308636 922387574
On-off Valve for silicon resuscitator	70-555-36		R03020201	n.d.	65022/R	923305825

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

1. The Device shown on this document fulfils the regulatory essential requirements to Annex I Directive 93/42/EEC;
2. The Device shown on this document belongs 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 readied in NOT STERILE package.
6. IT IS NOT ALLOWED to use/install the above mentioned Devices for any purposes other than the intended use indicated by FOR.ME.SA S.r.l.
7. All documentation proving the conformity to the Directive 93/42/CEE will be made available to the relevant authorities for five (5) years starting from the last date of production of the Device under discussion

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.

**2019, 18th february**

Place and date of issue

**FOR.ME.SA. SRL**

Via F.lli Canvelli, 6

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BIZZI DESOLINA

Signature and Company's Stamp

