

Noáin, 25th May 2021

CE DECLARATION OF CONFORMITY

Ms Silvia Munárriz Abadín, in representation of,


Shanae Servicios Geriátricos S.L.U, with tax address in C/ Arrieta, 27, 31002, Pamplona, Navarra, Spain with manufacturing address in Polígono Industrial Talluntxe II- C/ C, Nave 68, 31110 Noáin, Navarra, Spain.

SRN: ES-MF-000001503

Declares that the products listed in Annex I comply with the essential requirements applicable to them in accordance with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, so that the absence of compromise to the health and safety of the user of these products is guaranteed, provided that they are used in accordance with the intended purpose and following the instructions for use that accompany them.

Classification : **Class I** as defined in the Annex VIII of the Regulation (EU) 2017/745

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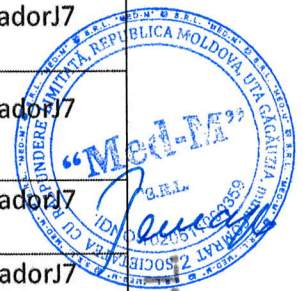


REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
DSB	Duo Security belt + pelvis	One size	843604205sujeciionsillaX3
AD08	Auxiliary wandering belt (6 handles)	One size	843604205sujeciionsillaX3
AD10	Pelvic abdominal fixing belt	One size	843604205sujeciionsillaX3
AD11	Abdominal fixing belt for chair with plastic buckle	0 - 1	843604205sujeciionsillaX3
AD11E	Abdominal fixing belt for chair, narrow, with plastic buckle	1	843604205sujeciionsillaX3
AD11M	Abdominal fixing belt for chair with magnetic closure	0 - 1	843604205sujeciionsillaX3
AD12	Perineal fixing belt for chair (plastic buckle)	0 - 1	843604205sujeciionsillaX3
AD12M	Perineal fixing belt for chair (magnetic closure)	0 - 1	843604205sujeciionsillaX3
AD13	Fixing belt for chair (torso) with plastic buckle	0 - 1	843604205sujeciionsillaX3
AD13M	Fixing belt for chair (torso) with magnetic closure	0 - 1	843604205sujeciionsillaX3
AD14	Fixing belt for chair (torso+pelvis) with plastic buckle	0 - 1	843604205sujeciionsillaX3
AD14M	Fixing belt for chair (torso+pelvis) with magnetic closure	0 - 1	843604205sujeciionsillaX3
AD15	Fixing vest for chair	M - L	843604205sujeciionsillaX3
AD16	Fixing belt "transfer"	M - L	843604205sujeciionsillaX3
AD17	Perineal vest for chair with plastic buckle	0 - 1	843604205sujeciionsillaX3
AD17P	Perineal vest, low cut, for chair , plastic buckle	0 - 1	843604205sujeciionsillaX3
AD17M	Perineal vest for chair with magnetic closure	0 - 1	843604205sujeciionsillaX3
AD18	Standard vest for chair with plastic buckle	0 - 1	843604205sujeciionsillaX3
AD18M	Standard vest for chair with magnetic closure	0 - 1	843604205sujeciionsillaX3

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REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
AD50	Abdom.fixing belt for chair/armchair, magnetic closure front, plastic buckle back	M - L	843604205sujeciionsillaX3
AD50M	Abdom.fixing belt for chair/armchair, magnetic closure front and back	M - L	843604205sujeciionsillaX3
AD52	Abdom.fixing belt for chair/armchair plastic buckle and hook	M-L	843604205sujeciionsillaX3
CAD16	Extension for wheelchair belts, plastic buckle	One size	843604205sujeciionsillaX3
CAD16M	Extension for wheelchair magnetic belts	One size	843604205sujeciionsillaX3
CAD17	Extension for vests	One size	843604205sujeciionsillaX3
ADX1	Foot supports for wheelchair	0 - 1 - 2	843604205posicionadorJ7
ADX2	Foot belt	0 - 1	843604205posicionadorJ7
ADX5	Calf Strap for wheelchair	One size	843604205posicionadorJ7
ADX6	Calf Strap for wheelchair with ankle support	One size	843604205posicionadorJ7
ADX20	Pelvic abdominal fixing belt, plastic buckle	00-0-1-2	843604205posicionadorJ7
ADX21	Pelvic abdominal fixing belt, safety closure	0 - 1 - 2	843604205posicionadorJ7
ADX22	Trunk Support with zip, screwed to the chair	00-0-1-2	843604205posicionadorJ7
ADX22C	Trunk suppor with zip, plastic buckle closure	00-0-1-2	843604205posicionadorJ7
ADX24	Trunk Support without zip, screwed to the chair	00-0-1-2	843604205posicionadorJ7
ADX24C	Trunk Support without zip, plastic buckle closure	00-0-1-2	843604205posicionadorJ7
ADX23	Shoulder harness, screwed to the chair	0-1-2	843604205posicionadorJ7
ADX23C	Shoulder harness, plastic buckle closure	0-1-2	843604205posicionadorJ7

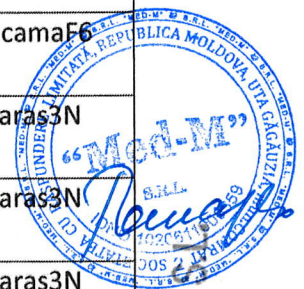


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REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
ADX30	Abduction Support	0-1	843604205posicionadorJ7
ADX31	Abduction Support, semirigid	0-1	843604205posicionadorJ7
ADX32	Leg harness	0-1	843604205posicionadorJ7
ADX39	Pelvic wrap	One size	843604205posicionadorJ7
ADX4PE	4 point pelvic fixing belt, plastic buckle	00-0-1-2	843604205posicionadorJ7
ADX4PS	4 point pelvic fixing belt, safety closure	0-1-2	843604205posicionadorJ7
ADX40	Lumbar positioning cushion	One size	843604205posicionadorJ7
AD51	Abdominal fixing belt for bed	S-M-L	843604205sujecioncamaF6
AD61	Wrist restraint for bed	One size	843604205sujecioncamaF6
AD66	Ankle restraint for bed	One size	843604205sujecioncamaF6
AD54	Abdominal fixing belt for bed, magnetic closure (polypropylene)	S-M-L	843604205sujecioncamaF6
AD56	Abdominal fixing belt for bed, magnetic closure	S-M-L	843604205sujecioncamaF6
AD56A	Abdominal fixing belt for bed, magnético closure, padded	S-M-L	843604205sujecioncamaF6
AD56P	Abdominal pelvic belt for bed with magnetic closure	S-M-L	843604205sujecioncamaF6
AD62	Wrist restraint with magnetic closure (pair)	One size	843604205sujecioncamaF6
AD67	Ankle restraint with magnetic closure (pair)	One size	843604205sujecioncamaF6

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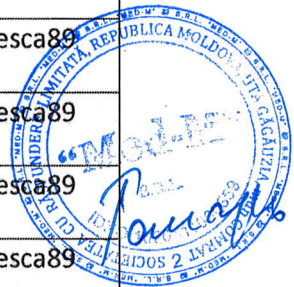
REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
AD55	Psychiatric fixing belt with magnetic closure	M-L	843604205sujecioncamaF6
AD58	Abdominal belt for strecher, magnetic closure	S-M-L	843604205sujecioncamaF6
AD68	Ankle restraint for strecher, magnetic closure	One size	843604205sujecioncamaF6
PEAD56	Pelvic accessory for AD56	One size	843604205sujecioncamaF6
PEAD54	Pelvic accessory for AD54	One size	843604205sujecioncamaF6
TAD54	Shoulder restrint for AD54	One size	843604205sujecioncamaF6
TAD56	Shoulder restraint for AD56	One size	843604205sujecioncamaF6
CTAD54	Additional shoulder restraint for AD54	One size	843604205sujecioncamaF6
CTAD56	Additional shoulder restraint for AD56	One size	843604205sujecioncamaF6
CAD54	Extension for AD54	One size	843604205sujecioncamaF6
CAD56	Extension for AD56	One size	843604205sujecioncamaF6
AD71	Silicone fiber Mitt (unit)	One size	843604205antiescaras3N
AD72	Standard mitt (pair)	One size	843604205antiescaras3N
AD73	Breathable mitt (pair)	One size	843604205antiescaras3N
AD76	Anti-decubitus heel/elbow pad (unit)	One size	843604205antiescaras3N
AD77	Anti-decubitus heel/elbow pad (big model) (unit)	One size	843604205antiescaras3N
AD80	Anti-decubitus sock (pair)	One size	843604205antiescaras3N
AD79	Suapel heel (unit)	One size	843604205antiescaras3N



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REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
AD90	Pyjama bed sheet (long sleeves)	One size	843604205sabanafantasmaWE
AD91	Pyjama bed sheet (short sleeves)	One size	843604205sabanafantasmaWE
AD92	Pyjama bed sheet (without sleeves)	One size	843604205sabanafantasmaWE
AD93	Geriatric pyjama (1 zip/long sleeves)	S-M-L	843604205pijamageriatr3Z
AD94	Geriatric pyjama (1 zip/short sleeves)	S-M-L	843604205pijamageriatr3Z
AD95	Geriatric pyjama (2 zips/long sleeves)	S-M-L	843604205pijamageriatr3Z
AD96	Geriatric pyjama (2 zips/short sleeves)	S-M-L	843604205pijamageriatr3Z
AD98	Hospital/geriatric gown	0-1	843604205camisongeriatrGB
AD99	Hospital/geriatric gown	0-1	843604205camisongeriatrGB
AD200	Rail protector for bed	One size	843604205protectorbaranMS
AD300	Sling for lifter standard	M-L	843604205arnesgrua47
AD450	Suapel cushion round with hole	One size	843604205cojinantiesca89
AD451	Suapel cushion horseshoe	One size	843604205cojinantiesca89
AD452	Suapel cushion square with hole	One size	843604205cojinantiesca89
AD453	Suapel cushion square	One size	843604205cojinantiesca89
AD454	Suapel cushion square horseshoe	One size	843604205cojinantiesca89
AD460	PU cushion round with hole	One size	843604205cojinantiesca89
AD461	PU cushion horseshoe	One size	843604205cojinantiesca89
AD462	PU cushion square with hole	One size	843604205cojinantiesca89

REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
AD463	PU cushion aquare	One size	843604205cojinantiesca89
AD464	PU cushion square horsehoe	One size	843604205cojinantiesca89
AD400	Visco elastic antidecubitus cushion	42x42x7cm	843604205cojinantiesca89
AD405	Visco elastic antidecubitus cushion	42x42x7cm	843604205cojinantiesca89
AD409	Visco anatomic cushion (weight máx: 90kg)	41x41x7cm 45x42x7cm	843604205cojinantiesca89
AD410	Visco anatomic cushion (weight máx: 100kg)	41x41x7cm 45x42x7cm	843604205cojinantiesca89
AD412	Visco anatomic cushion with coxis cut-out	43x42x7cm	843604205cojinantiesca89
AD415	Visco anatomic cushion with Outlast® treatment	41x41x7cm 45x42x7cm	843604205cojinantiesca89
AD420	Gel cushion	40x40x2,2cm	843604205cojinantiesca89
AD425	Gel 3D cushion	40X40cm 45x42cm	843604205cojinantiesca89
AD430	Visco-gel cushion	41x41x7cm 45x42x7cm	843604205cojinantiesca89
AD432	Visco-gel combi cushion	45x42x7cm	843604205cojinantiesca89
AD490	Cervical cushion (Cotton)	One size	843604205cojincervical77
AD491	Cervical cushion (Suapel)	One size	843604205cojincervical77
AD492	Cervical cushion (PU)	One size	843604205cojincervical77
1011	Soft cervical collar 75mm	One size	843604205collarcervica6y
1012	Soft cervical collar 95mm	One size	843604205collarcervica6y
1013	Soft cervical collar 75mm	1-2-3	843604205collarcervica6y

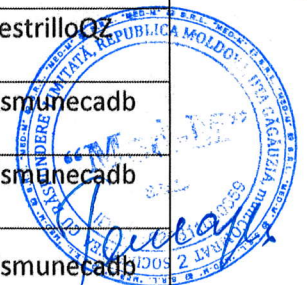


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REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
1014	Soft cervical collar 75mm	1-2-3-4-5	843604205collarcervica6y
1015	Soft cervical collar 100mm	1-2-3-4-5	843604205collarcervica6y
1020	Semirigid cervical collar 75mm	One size	843604205collarcervica6y
1100	Rigid cervical collar	1-2-3-4-5	843604205collarcervica6y
1110	Rigid cervical collar	1-2-3-4-5	843604205collarcervica6y
102	Thoracic binder	80-90-100- 110	843604205bandajestoyabkm
116	Standard thoracic binder	1-2-3-4	843604205bandajestoyabkm
117	Standard thoracic binder	One size	843604205bandajestoyabkm
120	Abdominal compression binder	1-2-3	843604205bandajestoyabkm
124	Abdominal standard binder 24cm	0-1-2-3-4	843604205bandajestoyabkm
132	Abdominal standard binder 32cm	0-1-2-3-4	843604205bandajestoyabkm
3022	Elastic lumbosacral belt	1-2-3-4-5-6	843604205fajaelasticaCM
3026	Elastic lumbosacral belt 26cm	1-2-3-4-5-6	843604205fajaelasticaCM
3032	Elastic lumbosacral belt – 32cm	1-2-3-4-5-6	843604205fajaelasticaCM
3025	Elastic sacrolumbar belt- 26cm	1-2-3-4-5-6	843604205fajaelasticaCM
3031	Elastic sacrolumbar belt	1-2-3-4-5-6	843604205fajaelasticaCM
3058	Elastic dorsolumbar belt	1-2-3-4-5-6	843604205fajaelasticaCM
3126	Faja sacro lumbar twin	1-2-3-4	843604205fajaelasticaCM
FT22	Lumbar support 22cm	1-2-3-4	843604205fajasemirigidQD
FT24	Lumbar support 24cm	1-2-3-4	843604205fajasemirigidQD

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REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
9026	Semirigid lumbosacral belt (26cm)	1-2-3-4-5	843604205fajasemirigidQD
9032	Semirigid lumbosacral belt (32cm)	1-2-3-4-5	843604205fajasemirigidQD
9050	Semirigid lumbosacral belt (50cm)	1-2-3-4-5	843604205fajasemirigidQD
141	Elastic shoulder support	1-2-3-4-5	843604205espaldillera28
142	Elastic shoulder support	1-2-3-4-5	843604205espaldillera28
151	Clavicle immobiliser	1-2-3-4-5	843604205inmovclavicula8G
152	Sling	One size	843604205cabestrilloQZ
153	Classic sling	1-2	843604205cabestrilloQZ
155	Classic sling	1-2	843604205cabestrilloQZ
157	Shoulder immobiliser sling	One size	843604205cabestrilloQZ
160	Wrist Support	1-2-3	843604205ortesismunecadb
161	Wrist Support	One size	843604205ortesismunecadb
165	Metacarpal wrist Support short (left or right)	1-2-3	843604205ortesismunecadb
167	Metacarpal wrist support long (left or right)	1-2-3	843604205ortesismunecadb
168	Metacarpal wrist Support (ambidextrous)	1-2-3	843604205ortesismunecadb
169	Thumb ambidextrous stabiliser Support	1-2	843604205ortesispulgarfa
190	Elastic ankle support	1-2-3	843604205tobilleraelastWY
191	Elastic ankle Support	One size	843604205tobilleraelastWY
560	Universal knee splint	0-1-2-3-4	843604205inmovrodillaNA



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REFERENCE	DESCRIPTION	SIZE	BASIC UDI-DI
AD501	Post-operativ knee splint (short or long)	One size	843604205rodilleraPostNV
2000	Adjustable hip abduction splint	12-14-16-18-20-22-24-26-28-30-32-34	843604205abductorcadera3A
6040	Inguinal truss	1-2-3	843604205bragueroinguinPU
HA STD	HeadActive Standard	One size	843604205sujecioncabezaZJ
HA TOW	HeadActive Tower	One size	843604205sujecioncabezaZJ
HA FIX	HeadActive Fix	One size	843604205sujecioncabezaZJ
HA SFT	HeadActive Soft	One size	843604205sujecioncabezaZJ
HA VRS	HeadActive Versa	One size	843604205sujecioncabezaZJ
HA DEM	HeadActive Demo	One size	843604205sujecioncabezaZJ
HP100	HeadPod Kit	One size	843604205sujecioncabezaZJ
HP102	HeadPod Kit mini	One size	843604205sujecioncabezaZJ
HP104	HeadPod Kit Max	One size	843604205sujecioncabezaZJ

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