



Ledraplastic^{spa}

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Osoppo
23/03/2022

LUDWIG BERTRAM GMBH
Im Torfstich 7
30916 ISERNHAGEN / KIRCHHORST
DEUTSCHLAND

Nome del fabbricante (Name of the manufacturer): **LEDRAPLASTIC S.P.A.**

Indirizzo del fabbricante (Address of the manufacturer): **Via Brigata Re, 1 - 33010 OSOPPO (UD) - ITALY**

GROUP 1

Palla gonfiabile idonea per attività motoria e psicomotoria ed attività fisioterapica

Inflatable ball suitable for motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
80.94	Gym Ball / magenta	8001698F1D01M1I1P0134	08001698080949	(10) LOT
95.45	Gymnic Classic 45 / yellow	8001698F1D01M1I1P0134	08001698095455	(10) LOT
95.55	Gymnic Classic 55 / red	8001698F1D01M1I1P0134	08001698095554	(10) LOT
95.65	Gymnic Classic 65 / blue	8001698F1D01M1I1P0134	08001698095653	(10) LOT
95.75	Gymnic Classic 75 / yellow	8001698F1D01M1I1P0134	08001698095752	(10) LOT
95.85	Physio Gymnic 85 / red	8001698F1D01M1I1P0134	08001698095851	(10) LOT
95.95	Physio Gymnic 95 / blue	8001698F1D01M1I1P0134	08001698095950	(10) LOT
95.98	Physio Gymnic 120 / red	8001698F1D01M1I1P0134	08001698095981	(10) LOT
96.55	Opti Ball 55 / transparent	8001698F1D01M1I1P0134	08001698096551	(10) LOT
96.65	Opti Ball 65 / transparent	8001698F1D01M1I1P0134	08001698096650	(10) LOT
96.75	Opti Ball 75 / transparent	8001698F1D01M1I1P0134	08001698096759	(10) LOT
96.95	Opti Ball 95 / transparent	8001698F1D01M1I1P0134	08001698096957	(10) LOT



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GROUP 2

Palla gonfiabile antiscoppio idonea per attività motoria e psicomotoria ed attività fisioterapica

Anti-burst inflatable ball suitable for motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
90.55	Body Ball 55 BRQ / red	8001698F1D01M2I1P013H	08001698090559	(10) LOT
90.65	Body Ball 65 BRQ / blue	8001698F1D01M2I1P013H	08001698090658	(10) LOT
90.75	Body Ball 75 BRQ / yellow	8001698F1D01M2I1P013H	08001698090757	(10) LOT
90.85	Body Ball 85 BRQ / red	8001698F1D01M2I1P013H	08001698090856	(10) LOT
90.95	Body Ball 95 BRQ / blue	8001698F1D01M2I1P013H	08001698090955	(10) LOT
91.85	Physio Gymnic Plus 85 BRQ / lime green	8001698F1D01M2I1P013H	08001698091853	(10) LOT
91.95	Physio Gymnic Plus 95 BRQ / lime green	8001698F1D01M2I1P013H	08001698091952	(10) LOT
91.98	Physio Gymnic Plus 120 BRQ / lime green	8001698F1D01M2I1P013H	08001698091983	(10) LOT
95.05	Fit-Ball 55 BRQ / pearl white	8001698F1D01M2I1P013H	08001698090509	(10) LOT
95.06	Fit-Ball 65 BRQ / pearl white	8001698F1D01M2I1P013H	080016980905066	(10) LOT
95.07	Fit-Ball 75 BRQ / pearl white	8001698F1D01M2I1P013H	080016980905073	(10) LOT
95.25	Gymnic Plus 65 BRQ / orange	8001698F1D01M2I1P013H	080016980905257	(10) LOT
95.26	Gymnic Plus 65 BRQ / purple	8001698F1D01M2I1P013H	080016980905264	(10) LOT
95.28	Gymnic Plus 55 BRQ / red	8001698F1D01M2I1P013H	080016980905288	(10) LOT
95.29	Gymnic Plus 65 BRQ / blue	8001698F1D01M2I1P013H	080016980905295	(10) LOT
95.30	Gymnic Plus 75 BRQ / yellow	8001698F1D01M2I1P013H	080016980905301	(10) LOT
95.35	Gymnic Arte 55 BRQ / multicolour	8001698F1D01M2I1P013H	080016980905356	(10) LOT
95.36	Gymnic Arte 65 BRQ / multicolour	8001698F1D01M2I1P013H	080016980905363	(10) LOT
95.37	Gymnic Arte 75 BRQ / multicolour	8001698F1D01M2I1P013H	080016980905370	(10) LOT
95.39	Gymnic Plus 55 BRQ / green	8001698F1D01M2I1P013H	080016980905394	(10) LOT
95.40	Gymnic Plus 65 BRQ/green	8001698F1D01M2I1P013H	080016980905400	(10) LOT
95.41	Gymnic Plus 75 BRQ / green	8001698F1D01M2I1P013H	080016980905417	(10) LOT
95.42	Gymnic Plus 65 BRQ / yellow	8001698F1D01M2I1P013H	080016980905424	(10) LOT
95.43	Gymnic Plus 65 BRQ / black	8001698F1D01M2I1P013H	080016980905431	(10) LOT



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GROUP 3

Palla gonfiabile antiscoppio con fondo bilanciato idonea per seduta ergonomica, attività motoria e psicomotoria ed attività fisioterapica

Anti-burst inflatable ball with balanced bottom, suitable for ergonomic sitting, motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
94.55	Memory Ball 55 BRQ / grey	8001698F1D02M2I1P0246	08001698094557	(10) LOT
94.65	Memory Ball 65 BRQ / grey	8001698F1D02M2I1P0246	08001698094656	(10) LOT



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GROUP 4

Palla gonfiabile contenente elementi visivi e sonori, idonea per stimolazione sensoriale visiva e uditiva, attività motoria, psicomotoria, ed attività fisioterapia

Inflatable ball containing visual and sound elements, suitable for sensory stimulation (visual and auditory), motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
96.02	Activity Ball / transparent	8001698F1D01M1I1P0338	08001698096025	(10) LOT
96.98	Jinglin' Ball / transparent	8001698F1D01M1I1P0338	08001698096988	(10) LOT



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GROUP 5

Palla gonfiabile con rilievi sensoriali tattili sulla superficie idonea per attività motoria, psicomotoria ed attività fisioterapica

Inflatable ball covered in tactile sensory bumps suitable for motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
97.60	Therasensory 100 / red	8001698F1D04M1I1P014V	08001698097602	(10) LOT
97.61	Therasensory 65 / green	8001698F1D04M1I1P014V	08001698097619	(10) LOT



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GROUP 6

Palla gonfiabile dotata di piedini idonea per seduta ergonomica, attività motoria e psicomotoria ed attività fisioterapica.

Inflatable ball equipped with little stability feet, suitable for ergonomic sitting, motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
89.35	Sit'n'Gym Jr. 35 / transparent w/stars	8001698F1D03M1I1P024C	08001698089355	(10) LOT
89.45	Sit'n'Gym Jr. 45 / yellow	8001698F1D03M1I1P024C	08001698089454	(10) LOT



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GROUP 7

Palla gonfiabile antiscoppio dotata di piedini idonea per seduta ergonomica, attività motoria e psicomotoria ed attività fisioterapica.

Anti-burst inflatable ball equipped with little stability feet, suitable for ergonomic sitting, motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
89.55	Sit'n'Gym 55 BRQ / red	8001698F1D03M2I1P024R	08001698089553	(10) LOT
89.65	Sit'n'Gym 65 BRQ / blue	8001698F1D03M2I1P024R	08001698089652	(10) LOT
89.75	Sit'n'Gym Perla 55 BRQ / pearl white	8001698F1D03M2I1P024R	08001698089751	(10) LOT
89.76	Sit'n'Gym Perla 65 BRQ / pearl white	8001698F1D03M2I1P024R	08001698089768	(10) LOT
89.77	Sit'n'Gym Perla 75 BRQ / pearl white	8001698F1D03M2I1P024R	08001698089775	(10) LOT



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GROUP 8

Palla doppia gonfiabile di forma allungata idonea per attività motoria, psicomotoria ed attività fisioterapia

Inflatable double ball with elongated shape suitable for motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
88.00	Physio Roll 30 / blue	8001698F2D01M1I1P0143	08001698088006	(10) LOT
88.01	Physio Roll 40 / red	8001698F2D01M1I1P0143	08001698088013	(10) LOT
88.02	Physio Roll 55 / yellow	8001698F2D01M1I1P0143	08001698088020	(10) LOT
88.03	Physio Roll 70 / blue	8001698F2D01M1I1P0143	08001698088037	(10) LOT
88.04	Physio Roll 85 / red	8001698F2D01M1I1P0143	08001698088044	(10) LOT



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GROUP 9

Palla doppia gonfiabile antiscoppio di forma allungata idonea per attività motoria, psicomotoria ed attività fisioterapica

Anti-burst inflatable double ball with elongated shape suitable for motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
88.12	Physio Roll Plus 55 BRQ / green	8001698F2D01M2I1P014G	08001698088129	(10) LOT
88.13	Physio Roll Plus 70 BRQ / blue	8001698F2D01M2I1P014G	08001698088136	(10) LOT



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GROUP 10

Palla doppia gonfiabile contenente elementi visivi e sonori idonea per la stimolazione sensoriale visiva e uditiva, attività motoria, psicomotoria, ed attività fisioterapia

Inflatable double ball containing visual and sound elements, suitable for sensory stimulation (visual and auditory), motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
88.05	Physio Activity Roll / transparent	8001698F2D01M1I1P0347	08001698088051	(10) LOT



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GROUP 11

Palla doppia gonfiabile di forma allungata con rilievi sensoriali tattili sulla superficie idonea per attività motoria, psicomotoria ed attività fisioterapica

Long shaped inflatable double ball covered in tactile sensory bumps, suitable for motor activity, psychomotricity and physiotherapy

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
88.06	Sens'o'Roll / orange	8001698F2D04M1I1P015U	08001698088068	(10) LOT



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GROUP 12

Cuscino gonfiabile cuneiforme idoneo per seduta ergonomica e come attrezzo propriocettivo e riabilitativo degli arti inferiori

Wedge-shaped inflatable cushion suitable for ergonomic sitting, proprioception activity and lower limb rehabilitation

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
89.07	Sit'on'Air / blue	8001698F3D05M11P047L	08001698089072	(10) LOT
89.09	Movin' Sit Jr. / blue	8001698F3D05M11P047L	08001698089096	(10) LOT
89.10	Movin' Sit / blue	8001698F3D05M11P047L	08001698089102	(10) LOT



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LUDWIG BERTRAM GMBH
Im Torfstich 7
30916 ISERNHAGEN / KIRCHHORST
DEUTSCHLAND

Nome del fabbricante (Name of the manufacturer): **LEDRAPLASTIC S.P.A.**

Indirizzo del fabbricante (Address of the manufacturer): **Via Brigata Re, 1 - 33010 OSOPPO (UD) - ITALY**

GROUP 13

Cuscino gonfiabile di forma lenticolare idoneo per seduta ergonomica e come attrezzo propriocettivo e riabilitativo degli arti inferiori

Lenticular shaped inflatable cushion suitable for ergonomic sitting, proprioception activity and lower limb rehabilitation

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
89.11	Disc'o'Sit / blue	8001698F3D06M1I1P0487	08001698089119	(10) LOT
89.12	Disc'o'Sit Jr. / red	8001698F3D06M1I1P0487	08001698089126	(10) LOT
89.15	Disc'o'Sit / dark grey	8001698F3D06M1I1P0487	08001698089157	(10) LOT



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GROUP 14

Cuscino gonfiabile semicilindrico idoneo per seduta ergonomica e supporto lombare

Semicylindrical inflatable cushion suitable for ergonomic sitting and lumbar support

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
88.08	Vita Roll / blue	8001698F3D07M1I1P058U	08001698088082	(10) LOT
89.13	Comfort'a'Back / blue	8001698F3D07M1I1P058U	08001698089133	(10) LOT



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GROUP 15

Palla con rilievi sensoriali tattili sulla superficie idonea per massaggio e per la stimolazione della circolazione

Ball covered in tactile sensory bumps suitable for massage and blood flow stimulation

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
97.55	Reflexball Gift 8 / green	8001698F4D04M1I2P068B	08001698097558	(10) LOT
97.70	Reflexball Set 6 / blue	8001698F4D04M1I2P068B	08001698097701	(10) LOT
97.71	Reflexball Set 8 / green	8001698F4D04M1I2P068B	08001698097718	(10) LOT
97.72	Reflexball Set 9 / blue	8001698F4D04M1I2P068B	08001698097725	(10) LOT
97.73	Reflexball Set 10 / green	8001698F4D04M1I2P068B	08001698097732	(10) LOT



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GROUP 16

Palla gonfiabile con rilievi sensoriali tattili sulla superficie idonea per massaggio e per la stimolazione della circolazione

Inflatable ball covered in tactile sensory bumps suitable for massage and blood flow stimulation

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
97.53	Aku Ball / green	8001698F4D04M1I1P0684	08001698097534	(10) LOT



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GROUP 17

Rullo gonfiabile con rilievi sensoriali tattili sulla superficie idoneo per massaggio e per la stimolazione della circolazione

Inflatable roll covered in tactile sensory bumps suitable for massage and blood flow stimulation

Ref.	Nome/Colore (Name/Color)	Basic UDI-DI	UDI-DI	UDI-PI
97.54	Activ Roll / dark grey	8001698F5D04M1I1P0693	08001698097541	(10) LOT
97.75	Reflex Roll / green	8001698F5D04M1I1P0693	08001698097756	(10) LOT



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Indirizzo del fabbricante (Address of manufacturer): **Via Brigata Re, 1 - 33010 OSOPPO (UD) - ITALY**

Con la presente si attesta che la presente dichiarazione di conformità UE è rilasciata sotto la responsabilità esclusiva del fabbricante.

Conformemente alle regole di cui all'Allegato VIII del Regolamento Europeo 745/2017 relativo ai dispositivi medici, qui si dichiara che tutti i dispositivi medici della presente dichiarazione di conformità UE appartengono alla classe di rischio I.

Con la presente si dichiara che tutti i dispositivi medici inclusi nella presente dichiarazione di conformità UE sono conformi al Regolamento Europeo sui Dispositivi Medici 745/2017.

Con la presente si dichiara che tutti i dispositivi medici inclusi nella presente dichiarazione di conformità UE sono conformi al Regolamento Europeo 1907/2006 concernente la registrazione, la valutazione, l'autorizzazione e la restrizione delle sostanze chimiche (REACH) e relative modifiche.

It is hereby stated that the present EU declaration of conformity is issued under the sole responsibility of the manufacturer.

In accordance to the rules set out in Annex VIII of the EU Medical Device Regulation 745/2017, it is hereby stated that all medical devices listed in the present EU declaration of conformity belong to the risk class I

It is hereby stated that all devices that are covered by the present EU declaration comply with the EU Medical Device Regulation 745/2017.

It is hereby stated that all medical devices included in the present EU declaration of conformity comply with the European Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and related amendments.

Ledraplastic S.p.A.

Nevio Cosani (President)