



Reg. Numero /
Reg. Number

MED 31097

Revisione /
Revision

10

Primo rilascio /
First issue date

2012-11-05

Valido da /
Valid from

2017-11-03

Scadenza /
Valid until

2024-05-25

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 1 di / of 7

Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

CHINESPORT S.p.A.

Sede Legale e Operativa / *Registered and Operational Headquarter:*

Via Croazia 2
33100 Udine, UD - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Apparecchi elettronici per diatermia / *Diathermy electronic devices*

Apparecchiature per ionoforesi ed elettrostimolazione / *Equipment for ionophoresis and electrosimulation*

Apparecchiature per magnetoterapia / *Equipment for magnetic therapy*

Apparecchiature per terapia con onda d'urto / *Equipment for shock-wave therapy*

Apparecchiature per trazione / *Traction equipments*

Apparecchiature per ultrasuonoterapia / *Equipment for ultrasounds therapy*

Cicloergometro gambe / Ciclo-armo-ergometro gambe e braccia / *Leg cycle ergometer / Arm and leg cycle ergometer*

Dispositivi per terapia combinata elettrostimolazione ed ultrasuoni / *Combined electro and ultrasound therapy devices*

Laser terapeutici e manipoli / *Therapeutical lasers and probes*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 25/05/2021 10:20:09



Organismo Notificato n. 0476
Notified Body nr. 0476



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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Apparecchi elettronici per diatermia / Diathermy electronic devices

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1108

Marca / Brandname:

CHINESPORT

Modello / Model:

TCARE

Tipologia / Medical Devices:

Apparecchiature per ionoforesi ed elettrostimolazione / Equipment for ionophoresis and electrosimulation

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1108, MDS 7010

Marca / Brandname:

MEDICSTIM 2 COMPLET

Codici / Codes:

EL 17053

Marca / Brandname:

MEDICSTIM 4 COMPLET

Codici / Codes:

EL 17054

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Chief Operating Officer
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2021-05-24

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Apparecchiature per magnetoterapia / Equipment for magnetic therapy

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1108, MDS 7010

Marca / Brandname:

MAGNETO 2

Codici / Codes:

EL17064

Marca / Brandname:

MAGNETO 4

Codici / Codes:

EL17065

Tipologia / Medical Devices:

Apparecchiature per terapia con onda d'urto / Equipment for shock-wave therapy

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1108, MDS 7010

Marca / Brandname:

SHOCK WAVE COMPACT EXCELLENT

Codici / Codes:

EL17177

Marca / Brandname:

SHOCK WAVE EXCELLENT

Codici / Codes:

EL17088

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
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Valid until

2024-05-25

Ultima modifica /
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2021-05-24

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CERTIFICATE

**Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate**

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Apparecchiature per trazione / Traction equipments

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1108

Marca / Brandname:

CHINESPORT

Modello / Model:

Eurotrak

Tipologia / Medical Devices:

Apparecchiature per ultrasuonoterapia / Equipment for ultrasounds therapy

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1108, MDS 7010

Marca / Brandname:

SONIC 1

Codici / Codes:

EL17056

Marca / Brandname:

SONIC 2

Codici / Codes:

EL17057

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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 25/05/2021 10:22:11



Organismo Notificato n. 0476
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2021-05-24

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Cicloergometro gambe / Ciclo-armo-ergometro gambe e braccia / Leg cycle ergometer / Arm and leg cycle ergometer

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1108

Marca / Brandname:

CHINESPORT

Modello / Model:

Motolife, Motolife Evo

Codici / Codes:

AR20011, AR20012

Tipologia / Medical Devices:

Dispositivi per terapia combinata elettrostimolazione ed ultrasuoni
therapy devices

/ Combined electro and ultrasound

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1108, MDS 7010

Marca / Brandname:

KOMBY

Codici / Codes:

EL17059

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Laser terapeutici e manipoli / Therapeutical lasers and probes

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1108, MDS 7010

Marca / Brandname:

FISIOLASER EXCELLENT 12W

Codici / Codes:

EL17087

Marca / Brandname:

FISIOLASER EXCELLENT 15W

Codici / Codes:

EL17089

Marca / Brandname:

FISIOLASER EXCELLENT 8W

Codici / Codes:

EL12086

Marca / Brandname:

FISIOLASER IRD

Codici / Codes:

EL17061

Marca / Brandname:

FISIOLASER IRD 2

Codici / Codes:

EL17062

Marca / Brandname:

FISIOLASER SCAN 500

Codici / Codes:

EL12081

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:22:51



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Kiwa Cermet Italia S.p.A.
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CERMET



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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Laser terapeutici e manipoli / Therapeutical lasers and probes

Marca / Brandname:

FISIOLASER SCAN HP4

Codici / Codes:

EL12079

Marca / Brandname:

FISIOLASER SCAN HP8

Codici / Codes:

EL12080

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia. Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey. L'allegato tecnico è parte integrante del presente Certificato./ The technical sheet is an integrating part of this Certificate.

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:23:12



Organismo Notificato n. 0476
Notified Body nr. 0476





Reg. Number	10009 - M	Valid From	2021-05-24
First issue date	2009-11-10	Last change date	2021-05-24
Valid until	2024-11-10		

Quality Management System Certificate
ISO 13485:2016

We certify that the Quality Management System of the Organization:

CHINESPORT S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design, production, placing on the market and servicing of medical devices for physiotherapy, rehabilitation and aids for people with reduced mobility.
Marketing and servicing of medical devices for physiotherapy, rehabilitation, and aids for people with reduced mobility.

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

The date of issuance of this certificate is the date of first issue by another accredited body
This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
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direzione e coordinamento di
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CERMET

CHINESPORT S.p.A.

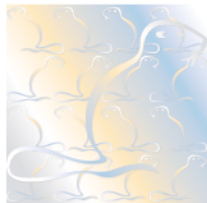
Registered Headquarters

- Via Croazia 2 33100 Udine - Italia

Certified Sites

- Via Croazia 2 33100 Udine - Italia





Reg. Number	10009 - A	Valid From	2021-05-24
First issue date	1998-01-26	Last change date	2021-05-24
Valid Until	2024-11-10	IAF Sector	19 , 29 a

Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

CHINESPORT S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design, production, placing on market and servicing of medical devices for physiotherapy, rehabilitation, and aids for people with reduced mobility.
Marketing and servicing of medical devices for physiotherapy, rehabilitation, and aids for people with reduced mobility.
Marketing and servicing of gymnastic equipment.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

The date of issuance of this certificate is the date of first issue by another accredited body
This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
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CHINESPORT S.p.A.

Registered Headquarters

- Via Croazia 2 33100 Udine - Italia

Certified Sites

- Via Croazia 2 33100 Udine - Italia



Object: environmental policy

As manager of the Department of Prevention & Protection, according to my capability, I shall ensure that the entire company structure of Chinesport SpA is eligible for the **Policy of Environmental Risk** in accordance to the Italian Legislative Decree numbers 81/2008 & 152/2006.

The company can be classified at a minimal risk as far as these environmental aspects are concerned:

- The limits of the outdoor noise pollution are respected
- Water for processes is not used
- Processes that involve outdoor air pollution are not executed (there is no need for exhaust nor gas extraction systems)
- The lighting system has been recently overhauled and updated, following a stringent policy of low energy consumption
- All waste is stringently stored in appropriate containers that are regularly disposed of by the Civil Public Service of NET Spa; in the case where waste does not follow such categories, we have always ensured their disposal through authorized companies, following the regulations of the current legislation (form, logbook, yearly Environmental Declaration Form).

In order to avoid or diminish occupational hazards, every worker of Chinesport SpA contributes with the employer establishment provisions and measures, to safeguard public health and the integrity of the **environment outdoors**.

Therefore, as part of the educational process and during simulation exercises we deal with the management of environmental emergencies, making the workers aware.

During the information and educational processes of the workers, we address the issue of waste management (from storage to transportation, to disposal); of air management: protection measures; of water management: protection measures.

For each worker of Chinesport SpA, therefore:

- It is prohibited the unchecked deposit and abandonment of waste in and on the soil; the waste is stored in the appropriate containers.
- It is prohibited the introduction of any type of waste, in a solid nor liquid state, on the water's surface nor underground.
- It is prohibited to mix the different categories of dangerous waste and/or dangerous waste with non-dangerous rubbish.
- Dangerous waste can be disposed of in the landfill only if previously classified and identified; during their transport, they shall be correctly labelled and delivered to companies authorized to the disposal process.
- During transport, "special and hazardous waste" shall be accompanied by an identification form according to the current Laws (Waste Identification Form) which enables the registration, traceability and monitoring of the waste.
- It is mandatory to report immediately eventual deficiencies found and/or any eventual conditions of environmental hazard they come across working, in cases of urgency, within their skill and within the limits of their abilities. This in order to remove or reduce the aforementioned deficiencies.
- Substances and preparations are kept labelled and it is necessary to ensure that in the workplace the Safety Data Sheet is available in Italian.
- Working conditions that restrict the development of powders, such as the moisturizing of semi-finished material, the use of manual or mechanical tools at a low speed, shall be adopted.
- Necessary precautions in conducting activities that can create triggering sources (e.g.: the use of grinders or others), shall be adopted.
- The appropriate screening measures to reduce noise, shall be adopted for all means of work that require it.
- The Municipal Regulation for the protection of noise pollution in a civil environment, shall be observed.
- In the case of underground pollution, with the possibility of aquifer pollution (e.g.: dangerous substance spills), the warning procedure to the competent authorities for the reclamation process, shall be acknowledged.
- In the case of an emergency, which could compromise the safety of third parties, the warning procedure to alert promptly the competent authorities (e.g.; The Fire Department, The Civil Defense, The Police, etc.), shall be acknowledged.

Dr. Mariangela Spitaleri –
RSPP Chinesport SpA



Udine. June 9th, 2016.

Dear Partner,

Subject: general warranty and possible extension

We declare that all medical devices presented in our range for Rehabilitation Equipment and Assistive Devices are under 24 months warranty from invoice date and in compliance with European standards (CE mark), where applicable.

We can grant extended warranty upon request when you consider that it's critical in order to compete with and promote our products, especially in case of public tender. Moreover we guarantee spare parts supply for 10 years from the invoice date.

The present statement is released for all possible commercial uses.

Yours sincerely,

CHINESPORT Spa - Italy



Mr. Angelo Snidero
(President and Managing Director)

Udine (Italy), 19th July 2021

QUALITY POLICY

Experience, highly qualified human resources, a constant and effective research program and the wide range and number of products available have made possible for CHINESPORT to become a leading company in the physiotherapy and rehabilitation field.

The future of CHINESPORT depends on these main factors:

- The high quality of products and services offered
- Collaborating with field experts (eg. orthopaedic technicians, physiotherapists, specialized physicians)
- The professionalism of its own sales network, including retailers
- The great competence of its personnel and the sales network's
- Customer satisfaction

Our company pays great attention to satisfying all product and service requirements needed.

This is the base of CHINESPORT's continuous improvement process in which each associate has an important role contributing with ideas and personal commitment. Furthermore, it is paramount to develop the ability to find joint solutions and develop a sense of feeling of belonging to a "work group", while maintaining the single company responsibilities.

Every year, specific measurable objectives are defined in correspondence with this policy.

CHINESPORT Management





TRADE MARKS:

GYMNIC
The Way to Move

FIT-BALL



Ledraplastic
spa

www.gymnic.com

E-mail: info@gymnic.com

P.E.C.: ledraplastic@postacerta.net

CAPITALE SOCIALE € 516.000 i.v.

33010 OSOPPO (UD) Italia - Via Brigata Re, 1

Tel. +39-0432-975051 - Fax +39-0432-975788

Cod. Fisc. / Part. IVA IT 00161320304 (TVA-VAT-MWS)

Reg. Imp. UD NR. 00161320304

C.C.I.A.A. Udine REA n. 85305 M. UD001249

Banks:

BANCA ANTONVENETA SPA fil. OSOPPO (UD)

IBAN IT 17 N 05040 64010 000001174536

SWIFT ANT BIT 2P 89B

OSOPPO, LI 26.06.2013

VS. RIF.

NS. RIF. NC/lm

DA CITARE NELLA RISPOSTA

CHINESPORT SPA
Via Croazia, 2
33100 UDINE

To whom it may concern

We, LEDRAPLASTIC SPA – Via Brigata Re, 1 – 33010 OSOPPO (UD) – ITALY (firm registration number: UD – 85305), hereby declare that our products are MADE IN ITALY, tested and that:

- They are conform to the European norm nr. 2009/48/EC (safety of toys)
- They are conform to the REACH regulation on banned phthalates (Directive nr. EC 1907/2006)
- They are LATEX free
- They are CE marked

We remain at your disposal for any further information.

Yours faithfully,

LEDRAPLASTIC S.P.A.
Nevio Cosani

**DICHIARAZIONE DI CONFORMITÀ - DECLARATION OF CONFORMITY
DÉCLARATION DE CONFORMITÉ – DECLARACIÓN DE CONFORMIDAD
KONFORMITÄTSERKLÄRUNG**

SECONDO LA DIRETTIVA 2001/95/CE
ACCORDING TO THE DIRECTIVE 2001/95/CE
SELON LA DIRECTIVE 2001/95/CE
SEGÚN LA DIRECTIVA 2001/95/CE
GEMÄß DER RICHTLINIE 2001/95/EG



Codice articolo / Product code / Code de l'article / Código del artículo / Artikelnummer	10400. - MATERASSINO cm 200 x 100 x 5 h MAT cm 200 x 100 x 5 h 10430. - MATERASSINO cm 200 x 100 x 10 h MAT cm 200 x 100 x 10 h 10490. - MATERASSINO cm 200 x 140 x 3 h MAT cm 200 x 140 x 3 h 10410. - MATERASSINO cm 200 x 140 x 5 h MAT cm 200 x 140 x 5 h 10420. - MATERASSINO cm 200 x 200 x 5 h MAT cm 200 x 200 x 5 h
Denominazione prodotto - Product name - Dénomination du produit – Denominación del producto - Produktname	Materassino
Fabbricante – Manufacturer - Producteur – Productor - Hersteller	CHINESPORT Spa – Via Croazia 2 33100 Udine - Italy
<p>I dispositivi sopra elencati sono conformi ai requisiti essenziali della direttiva 2001/95/CE The devices listed above comply with the essential requirements of MDD 2001/95/CE Les dispositifs du dessous sont conformes aux qualités essentielles de la 2001/95/CE. Los dispositivos sobre listados son conformes a los requisitos esenciales de la Directiva 2001/95/CE Die oben aufgeführten Geräte sind in Übereinstimmung mit den grundlegenden Anforderungen der Richtlinie 2001/95/CE</p>	

Udine (Italy), 2016.1.16

CHINESPORT S.P.A.

Angelo Snidero
(CEO)



[EN] According to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

[IT] In accordo con il REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO
[ES] De acuerdo con el REGLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO
[DE] Gemäß VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES
[FR] Conformément au RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL



MANUFACTURER	REGISTERED OFFICE	SRN
FABBRICANTE PRODUCTOR HERSTELLER PRODUCTEUR	SEDE LEGALE OFICINA REGISTRADA SIÈGE SOCIAL REGISTRIERTES BÜRO	NUMERO DI REGISTRAZIONE UNICO NÚMERO DE REGISTRO ÚNICO EINMALIGE REGISTRIERUNGSNUMMER NUMÉRO D'ENREGISTREMENT UNIQUE
CHINESPORT SPA	Via Croazia, 2 33100 – Udine (ITALY)	IT-MF-000005909

[EN] This declaration of conformity EU is issued under the sole responsibility of the manufacturer

[IT] La presente dichiarazione di conformità UE è rilasciata sotto la responsabilità esclusiva del fabbricante.
[ES] Esta declaración de conformidad de la UE se emite bajo la responsabilidad exclusiva del fabricante.
[DE] Diese EU-Konformitätserklärung wird in der alleinigen Verantwortung des Herstellers ausgestellt
[FR] Cette déclaration de conformité UE est émise sous la seule responsabilité du fabricant

Basic UDI-DI	80518810XDLD0001PF		RISK CLASS	I
UDI-DI BASE UDI-DI BÁSICO BASIS-UDI-DI IUD-ID			CLASSE DI RISCHIO CLASE DE RIESGO RISIKOKLASSE CLASSE DE RISQUE	
PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	
SPINE-LEG TOOLKIT	05006	GONIOMETER ALGO-GONIOMETRO	05000	
PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	
FOOT SIZE INDICATOR INDICATORE PIEDE	05001	TORSION METER TORSIOMETRO	05002	
PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	
D'OSUALDO ARCOMETER ARCOMETRO D'OSUALDO	05003	POSTURAL CALIBER CALIBRO BRACCI LUNGHI	05004	
PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	
DELTA LEG N	05005	ILIAC CRESTS ANALYSER ANALIZZATORE	06830	
PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	PRODUCT NAME NOME DEL PRODOTTO NOMBRE DEL PRODUCTO PRODUKTNAME NOM DU PRODUIT	PRODUCT CODE CODICE DEL PRODOTTO CÓDIGO DE PRODUCTO PRODUKTCODE CODE PRODUIT	
D'OSUALDO INCLINOMETER INCLINOMETRO D'OSUALDO	06855	GONIOMETRO RETROPIEDE GONIOMETRO RETROPIEDE	02049	
[EN] INTENDED USE Postural assessment devices	[IT] DESTINAZIONE D'USO Dispositivi per valutazione posturale	[ES] USO PREVISTO Dispositivos de evaluación postural	[DE] VERWENDUNGSZWECK Geräte zur Beurteilung der Körperhaltung	[FR] UTILISATION PRÉVUE Appareils d'évaluation posturale

COMMON SPECIFICATIONS [CS]

SPECIFICHE COMUNI | ESPECIFICACIONES COMUNES | GEMEINSAME
SPEZIFIKATIONEN | SPÉCIFICATIONS COMMUNES

-

[EN] We hereby declare that the devices listed above comply with the essential safety and performance requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 concerning medical devices (MDR).

[IT] Con la presente si dichiara che i dispositivi sopra elencati sono conformi ai requisiti essenziali di sicurezza e prestazione del REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO DEL 5 APRILE 2017 relativo ai dispositivi medici (MDR).
[ES] Por la presente declaramos que los dispositivos enumerados anteriormente cumplen con los requisitos esenciales de seguridad y rendimiento del REGLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO DE 5 DE ABRIL DE 2017 relativo a dispositivos médicos (MDR).

[DE] Hiermit erklären wir, dass die oben aufgeführten Geräte den grundlegenden Sicherheits- und Leistungsanforderungen der VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES VOM 5. APRIL 2017 in Bezug auf Medizinprodukte (MDR) entsprechen.

[FR] Nous déclarons par la présente que les dispositifs énumérés ci-dessus sont conformes aux exigences essentielles de sécurité et de performance du RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL DU 5 AVRIL 2017 relatif aux dispositifs médicaux (MDR)

[EN] This declaration is valid for the device used with the following accessories

[IT] La presente dichiarazione è valida per il prodotto usato con i seguenti accessori

[ES] Esta declaración es válida para el dispositivo utilizado con los siguientes accesorios

[DE] Diese Erklärung gilt für das Gerät, das mit folgendem Zubehör verwendet wird

[FR] Cette déclaration est valable pour l'appareil utilisé avec les accessoires suivants

COD.	DESCRIPTION	DESCRIZIONE
06810	PLUMBLINE	FILO A PIOMBO

[EN] Compliance is assessed in accordance with Annex IX by means of the applicable parts of the following standards:

[IT] La conformità è valutata in accordo all'allegato IX mediante le parti applicabili delle seguenti norme:

[ES] El cumplimiento se evalúa de acuerdo con el anexo IX mediante las partes aplicables de las siguientes normas:

[DE] Die Einhaltung wird gemäß Anhang IX anhand der anwendbaren Teile der folgenden Normen bewertet:

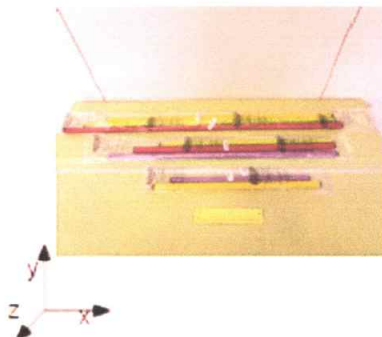
[FR] La conformité est évaluée conformément à l'annexe IX au moyen des parties applicables des normes suivantes:

EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices Evaluation and testing within a risk management process
EN 62366-1:2015+A1:2020	Medical devices Application of usability engineering to medical devices

Udine (Italy), 2021.05.28
Mr. Angelo Snidero
(CEO)



EU DECLARATION OF CONFORMITY



X= 1210 mm; Y= 24 mm; Z= 24 mm

Art. 0072-0080 - GYMNASTIC POLE

Name and address of manufacturer: **ITALVENETA DIDATTICA SRL**

Via Risorgimento 32
30010 PEGOLOTE DI CONA

This declaration of conformity is issued under the sole responsibility of the manufacturer:

The item object of the present declaration is in conformity with the relevant Union harmonisation legislation:

- 2009/48/EC Safety of Toys Directive

References to relevant harmonised standards used in relation to which conformity is declared:

EN 71-1:2014 + A1:2018, EN 71-2:2011 + A1:2014, EN 71-3:2019

Additional Information:

Signed for and on behalf of:

Place and date of issue:

Name and position:

ITALVENETA DIDATTICA SRL
Pegolotte di Cona, 02/07/2020
Elisa Ispato – Legale rappresentante

Elisa Ispato
ITALVENETA DIDATTICA SRL
Via Risorgimento 32
Pegolotte di Cona (VE)
Partita Iva 03236270272

DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ - DÉCLARATION DE CONFORMITÉ - DECLARACIÓN DE CONFORMIDAD - KONFORMITÄTSERLÄRUNG

ACCORDING TO THE DIRECTIVE 2001/95/CE

SECONDO LA DIRETTIVA 2001/95/CE

SELON LA DIRECTIVE 2001/95/CE

SEGÚN LA DIRECTIVA 2001/95/CE

GEMÄß DER RICHTLINIE 2001/95/EG



MANUFACTURER FABBRICANTE - PRODUCTEUR - PRODUTOR - HERSTELLER	CHINESPORT SPA
REGISTERED OFFICE SEDE LEGALE - SIÈGE SOCIAL - OFICINA REGISTRADA REGISTRIERTES BÜRO	Via Croazia, 2 33100 - Udine (ITALY)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

La presente dichiarazione è rilasciata sotto la responsabilità esclusiva del fabbricante.

Cette déclaration est émise sous la seule responsabilité du fabricant.

Esta declaración se emite bajo la exclusiva responsabilidad del fabricante.

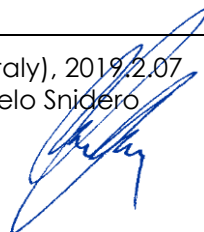
Diese Erklärung liegt in der alleinigen Verantwortung des Herstellers

PRODUCT CODE CODICE DEL PRODOTTO CODE PRODUIT CÓDIGO DE PRODUCTO PRODUKTCODE	PRODUCT NAME NOME DEL PRODOTTO - NOM DU PRODUIT - NOMBRE DEL PRODUCTO - PRODUKTNAME
10321.W*	LORDOSIS SUPPORT- W 29 x D 14 x H 5
10300.W*	HALF-CYLINDER 1- W 48 x D 25 x H 18
10310.W*	HALF-CYLINDER 2- W 60 x D 40 x H 18
09940.W*	CUBE 1- W 40 x D 40 x H 40
09950.W*	CUBE 2- W 50 x D 50 x H 50
09700.W*	RECTANGLE 1- W 40 x D 20 x H 10
09730.W*	RECTANGLE 2- W 40 x D 30 x H 5
09740.W*	RECTANGLE 3- W 40 x D 30 x H 10
09820.W*	RECTANGLE 4- W 80 x D 40 x H 40
09600.W*	WEDGE 1- W 25 x D 25 x H 10
09610.W*	WEDGE 2- W 35 x D 35 x H 10
09620.W*	WEDGE 3- W 60 x D 45 x H 15
09630.W*	WEDGE 4- W 60 x D 45 x H 30
09640.W*	WEDGE 5- W 60 x D 60 x H 15
09650.W*	WEDGE 6- W 60 x D 60 x H 20
10000.W*	CYLINDER 1- W 20 x Ø 8
10010.W*	CYLINDER 2- W 35 x Ø 15
10020.W*	CYLINDER 3- W 50 x Ø 15
10030.W*	CYLINDER 4- W 50 x Ø 25
10050.W*	CYLINDER 5- W 100 x Ø 25
10130.W*	RIGID ROLL 1- W 100 x Ø 30
10150.W*	RIGID ROLL 2- W 100 x Ø 40
10160.W*	RIGID ROLL 3- W 100 x Ø 50
10200.W*	RIGID ROLL 4- W 50 x Ø 30
11250.W*	LEG PILLOW - W 77 x D 50 x H 20/15
AC0024.W*	FACE CUSHION - W 31 x D 23 x H 6
AC0025.W*	CUSHION WITH HOLE - W 40 x D 34 x H 9
AC0881.W*	FACE CUSHION 2 - W 29 x D 31 x H 9
AC0966.W*	SHAPED CUSHION
AC0967.W*	SHAPED LONG CUSHION

INTENDED USE DESTINAZIONE D'USO - UTILISATION PRÉVUE - USO PREVISTO - VERWENDUNGSZWECK	Postural cushions Cuscini posturali
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*color option Colori - couleurs - colores - farben	A N 8 7 K S B 4 T 1 6 E Z G F H 9 Q R 2 3 L M P
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Udine (Italy), 2019/2/07
Mr. Angelo Snidero
(CEO)





EU Declaration of Conformity

Legal Manufacturer: MVS In Motion bv,
with registered office at: Westdijk 150, 2830 Tisselt (Willebroek), Belgium,
with SRN: BE-MF-000000664
declares under its sole responsibility that products listed below meet the provisions of
Medical Device Regulation 2017/745
as a Class I Medical Device,
according to Rule 1 of Annex VIII.

Intended purpose:

- Intended to increase (restore) range of motion, specifically for fingers;
- Intended to strengthen hand and finger muscles;

Conformity Assessment Route: Annex II & III of the Medical Device Regulation 2017/745.

List of Products:

REF	Description	BUDI-DI	UDI-DI
02-090101	MoVeS Comfort Putty Anti-Microbial 85g Super Soft - White	542006300E37	05420063002370
02-090102	MoVeS Comfort Putty Anti-Microbial 85g Extra Soft - Tan	542006300E37	05420063002387
02-090103	MoVeS Comfort Putty Anti-Microbial 85g Soft - Yellow	542006300E37	05420063002394
02-090104	MoVeS Comfort Putty Anti-Microbial 85g Medium Red	542006300E37	05420063002400
02-090105	MoVeS Comfort Putty Anti-Microbial 85g Firm - Green	542006300E37	05420063002417
02-090106	MoVeS Comfort Putty Anti-Microbial 85g Extra Firm - Blue	542006300E37	05420063002424
02-090401	MoVeS Comfort Putty Anti-Microbial 454g Super Soft - White	542006300E37	05420063002554
02-090402	MoVeS Comfort Putty Anti-Microbial 454g Extra Soft - Tan	542006300E37	05420063002561
02-090403	MoVeS Comfort Putty Anti-Microbial 454g Soft - Yellow	542006300E37	05420063002578
02-090404	MoVeS Comfort Putty Anti-Microbial 454g Medium Red	542006300E37	05420063002585
02-090405	MoVeS Comfort Putty Anti-Microbial 454g Firm - Green	542006300E37	05420063002592
02-090406	MoVeS Comfort Putty Anti-Microbial 454g Extra Firm - Blue	542006300E37	05420063002608

Date: 06 May 2021

Place: Tisselt (Willebroek), Belgium

Alexandra Vrancaert, General Manager



MVS In Motion
Westdijk 150
2830 Tisselt (Willebroek)
Belgium
SRN: BE-MF000000664

Declaration of Conformity

Manufacturers Name: MVS In Motion

Manufacturers Address: Westdijk 150
2830 Tisselt (Willebroek)
Belgium – Europe
SRN: BE-MF000000664

UK REP: Qarad UK Ltd.
8 Northumberland Ave
Westminster, London WC2N 5BY
United Kingdom

Classification: Class I, Rule 1, in accordance with rules set out in
Annex VIII of the MDR EU 2017/745

BUDI-DI: 542006300A2X

Name of the Devices:

REF	Description
01-100001	MoVeS Loop Extra Light - Tan 30 x 2,5 cm 10-pack
01-100002	MoVeS Loop Light - Yellow 30 x 2,5 cm 10-pack
01-100003	MoVeS Loop Medium - Red 30 x 2,5 cm 10-pack
01-100004	MoVeS Loop Heavy - Green 30 x 2,5 cm 10-pack
01-100005	MoVeS Loop Extra Heavy - Blue 30 x 2,5 cm 10-pack
01-100006	MoVeS Loop Special Heavy - Black 30 x 2,5 cm 10-pack
01-100011	MoVeS Loop Set 1 of Each resist.(Yellow to Blue) in mesh bag
01-100071	MoVeS Wide Loop Extra Light - Tan 30 x 7,5 cm (10-pack)
01-100072	MoVeS Wide Loop Light - Yellow 30 x 7,5 cm (10-pack)
01-100073	MoVeS Wide Loop Medium - Red 30 x 7,5 cm (10-pack)
01-100074	MoVeS Wide Loop Heavy - Green 30 x 7,5 cm (10-pack)
01-100075	MoVeS Wide Loop Extra Heavy - Blue 30 x 7,5 cm (10-pack)
01-100076	MoVeS Wide Loop Special Heavy - Black 30 x 7,5 cm (10-pa
01-100102	MoVeS Band 1,5m Dispenser Box of 25 pcs Light - Yellow

01-100103	MoVeS Band 1,5m Dispenser Box of 25 pcs Medium - Red
01-100104	MoVeS Band 1,5m Dispenser Box of 25 pcs Heavy - Green
01-100105	MoVeS Band 1,5m Dispenser Box of 25 pcs Extra Heavy - Blue
01-100106	MoVeS Band 1,5m Dispenser Box of 25 pcs Special Heavy -
01-100202	MoVeS Band 2,5m Light - Yellow 10-pack
01-100203	MoVeS Band 2,5m Medium - Red 10-pack
01-100204	MoVeS Band 2,5m Heavy - Green 10-pack
01-100205	MoVeS Band 2,5m Extra Heavy - Blue 10-pack
01-100206	MoVeS Band 2,5m Special Heavy - Black 10-pack
01-100207	MoVeS Band 2,5m Super Heavy - Silver 10-pack
01-100211	MoVeS Band 2,5m 1 of Each Resistance (Yellow to Black)
01-100501	MoVeS Band 5,5m Extra Light - Tan
01-100502	MoVeS Band 5,5m Light - Yellow
01-100503	MoVeS Band 5,5m Medium - Red
01-100504	MoVeS Band 5,5m Heavy - Green
01-100505	MoVeS Band 5,5m Extra Heavy - Blue
01-100506	MoVeS Band 5,5m Special Heavy - Black
01-100507	MoVeS Band 5,5m Super Heavy - Silver
01-100508	MoVeS Band 5,5m Ultra Heavy - Gold
01-101502	MoVeS Band 1,5m Light - Yellow 10-pack
01-101503	MoVeS Band 1,5m Medium - Red 10-pack
01-101504	MoVeS Band 1,5m Heavy - Green 10-pack
01-101505	MoVeS Band 1,5m Extra Heavy - Blue 10-pack
01-101506	MoVeS Band 1,5m Special Heavy - Black 10-pack
01-101507	MoVeS Band 1,5m Super Heavy - Silver 10-pack
01-101511	MoVeS Band 1,5m 1 of Each Resistance (Yellow to Black)
01-102202	MoVeS Band 22,5m Light - Yellow
01-102203	MoVeS Band 22,5m Medium - Red
01-102204	MoVeS Band 22,5m Heavy - Green
01-102205	MoVeS Band 22,5m Extra Heavy - Blue
01-102206	MoVeS Band 22,5m Special Heavy - Black
01-102207	MoVeS Band 22,5m Super Heavy - Silver
01-102208	MoVeS Band 22,5m Ultra Heavy - Gold
01-104501	MoVeS Band 45,5m Extra Light - Tan
01-104502	MoVeS Band 45,5m Light - Yellow
01-104503	MoVeS Band 45,5m Medium - Red
01-104504	MoVeS Band 45,5m Heavy - Green
01-104505	MoVeS Band 45,5m Extra Heavy - Blue
01-104506	MoVeS Band 45,5m Special Heavy - Black
01-110002	MoVeS F!T Loop Light - Peach 30 x 2,5 cm 10-pack
01-110003	MoVeS F!T Loop Medium - Orange 30 x 2,5 cm 10-pack
01-110004	MoVeS F!T Loop Heavy - Lime Green 30 x 2,5 cm 10-pack
01-110005	MoVeS F!T Loop Extra Heavy - Blueberry 30 x 2,5 cm 10-
01-110011	MoVeS F!T Loop Set 1 of Each resist.(Peach to Blueb) Mesh
01-110202	MoVeS F!T Band 2,5m Light - Peach 10-pack

01-110203	MoVeS F!T Band 2,5m Medium - Orange 10-pack
01-110204	MoVeS F!T Band 2,5m Heavy - Lime Green 10-pack
01-110205	MoVeS F!T Band 2,5m Extra Heavy - Blueberry 10-pack
01-110206	MoVeS F!T Band 2,5m Special Heavy - Plum 10-pack
01-110207	MoVeS F!T Band 2,5m Super Heavy - Gray 10-pack
01-110211	MoVeS F!T Band 2,5m 1 of Each Resistance (Peach to Plum)
01-110402	MoVeS F!T Superloop Light - Peach 104 cm
01-110403	MoVeS F!T Superloop Medium - Orange 104 cm
01-110404	MoVeS F!T Superloop Heavy - Lime Green 104 cm
01-110405	MoVeS F!T Superloop Extra Heavy - Blueberry 104 cm
01-110406	MoVeS F!T Superloop Special Heavy - Plum 104 cm
01-110502	MoVeS F!T Band 5,5m Peach - Light
01-110503	MoVeS F!T Band 5,5m Orange - Medium
01-110504	MoVeS F!T Band 5,5m Lime Green - Heavy
01-110505	MoVeS F!T Band 5,5m Blueberry - Extra Heavy
01-110506	MoVeS F!T Band 5,5m Plum - Special Heavy
01-110507	MoVeS F!T Band 5,5m Gray - Super Heavy
01-111502	MoVeS F!T Band 1,5m Light - Peach 10-pack
01-111503	MoVeS F!T Band 1,5m Medium - Orange 10-pack
01-111504	MoVeS F!T Band 1,5m Heavy - Lime Green 10-pack
01-111505	MoVeS F!T Band 1,5m Extra Heavy - Blueberry 10-pack
01-111506	MoVeS F!T Band 1,5m Special Heavy - Plum 10-pack
01-111507	MoVeS F!T Band 1,5m Super Heavy - Gray 10-pack
01-111511	MoVeS F!T Band 1,5m 1 of Each Resistance (Peach to Plum)
01-112207	MoVeS F!T Band 22,5m Gray - Super Heavy
01-114502	MoVeS F!T Band 45,5m Peach - Light
01-114503	MoVeS F!T Band 45,5m Orange - Medium
01-114504	MoVeS F!T Band 45,5m Lime Green - Heavy
01-114505	MoVeS F!T Band 45,5m Blueberry - Extra Heavy
01-114506	MoVeS F!T Band 45,5m Plum - Special Heavy
01-120502	MoVeS Band LATEX-FREE 5,5m Light - Yellow
01-120503	MoVeS Band LATEX-FREE 5,5m Medium - Red
01-120504	MoVeS Band LATEX-FREE 5,5m Heavy - Green
01-120505	MoVeS Band LATEX-FREE 5,5m Extra Heavy - Blue
01-120506	MoVeS Band LATEX-FREE 5,5m Special Heavy - Black
01-121502	MoVeS Band LATEX-FREE 1,5m Light - Yellow 10-pack
01-121503	MoVeS Band LATEX-FREE 1,5m Medium - Red 10-pack
01-121504	MoVeS Band LATEX-FREE 1,5m Heavy - Green 10-pack
01-121505	MoVeS Band LATEX-FREE 1,5m Extra Heavy - Blue 10-pack
01-121506	MoVeS Band LATEX-FREE 1,5m Special Heavy - Black 10-pa
01-121511	MoVeS Band LATEX-FREE 1,5m 1 of Each Resistance (Yellow
01-124502	MoVeS Band LATEX-FREE 45,5m Light - Yellow
01-124503	MoVeS Band LATEX-FREE 45,5m Medium - Red
01-124504	MoVeS Band LATEX-FREE 45,5m Heavy - Green
01-124505	MoVeS Band LATEX-FREE 45,5m Extra Heavy - Blue

01-124506	MoVeS Band LATEX-FREE 45,5m Special Heavy - Black
01-600101	MoVeS Bar Extra Light - Tan
01-600102	MoVeS Bar Light - Yellow
01-600103	MoVeS Bar Medium - Red
01-600104	MoVeS Bar Heavy - Green
01-600105	MoVeS Bar Extra Heavy - Blue
01-600106	MoVeS Bar Special Heavy - Black
01-200102	MoVeS Tube 120cm Handles Light - Yellow
01-200103	MoVeS Tube 120cm Handles Medium - Red
01-200104	MoVeS Tube 120cm Handles Heavy - Green
01-200105	MoVeS Tube 120cm Handles Extra Heavy - Blue
01-200106	MoVeS Tube 120cm Handles Special Heavy - Black
01-200107	MoVeS Tube 120cm Handles Super Heavy - Silver
01-200202	MoVeS O-Ring Tube Light - Yellow
01-200203	MoVeS O-Ring Tube Medium - Red
01-200204	MoVeS O-Ring Tube Heavy - Green
01-200205	MoVeS O-Ring Tube Extra Heavy - Blue
01-200206	MoVeS O-Ring Tube Special Heavy - Black
01-200302	MoVeS 8-Ring Tube Light - Yellow
01-200303	MoVeS 8-Ring Tube Medium - Red
01-200304	MoVeS 8-Ring Tube Heavy - Green
01-200305	MoVeS 8-Ring Tube Extra Heavy-Blue
01-200306	MoVeS 8-Ring Tube Special Heavy-Black
01-200402	MoVeS Cuff-Ring Tube Light - Yellow
01-200403	MoVeS Cuff-Ring Tube Medium - Red
01-200404	MoVeS Cuff-Ring Tube Heavy - Green
01-200405	MoVeS Cuff-Ring Tube Extra Heavy -Blue
01-200406	MoVeS Cuff-Ring Tube Special Heavy-Black
01-200702	MoVeS Tube 7,5m Light - Yellow
01-200703	MoVeS Tube 7,5m Medium - Red
01-200704	MoVeS Tube 7,5m Heavy - Green
01-200705	MoVeS Tube 7,5m Extra Heavy - Blue
01-200706	MoVeS Tube 7,5m Special Heavy - Black
01-200707	MoVeS Tube 7,5m Super Heavy - Silver
01-203002	MoVeS Tube 30m Light - Yellow
01-203003	MoVeS Tube 30m Medium - Red
01-203004	MoVeS Tube 30m Heavy - Green
01-203005	MoVeS Tube 30m Extra Heavy - Blue
01-203006	MoVeS Tube 30m Special Heavy - Black
01-203007	MoVeS Tube 30m Super Heavy - Silver
01-210102	MoVeS F!T Tube 120cm Handles Light - Peach
01-210103	MoVeS F!T Tube 120cm Handles Medium - Orange
01-210104	MoVeS F!T Tube 120cm Handles Heavy - Lime Green
01-210105	MoVeS F!T Tube 120cm Handles Extra Heavy - Blueberry
01-210106	MoVeS F!T Tube 120cm Handles Special Heavy - Plum

01-210107	MoVeS F!T Tube 120cm Handles Super Heavy - Gray
01-213002	MoVeS F!T Tube 30m Light - Peach
01-213003	MoVeS F!T Tube 30m Medium - Orange
01-213004	MoVeS F!T Tube 30m Heavy - Lime Green
01-213005	MoVeS F!T Tube 30m Extra Heavy - Blueberry
01-213006	MoVeS F!T Tube 30m Special Heavy - Plum
01-213007	MoVeS F!T Tube 30m Super Heavy - Gray

This declaration of conformity is issued under the sole responsibility of MVS In Motion.
We hereby declare that the medical devices specified above meet the relevant general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745

All Supporting documentation is retained at the premises of the manufacturer.

Place and date of issue: Willebroek, Belgium, 02/01/2023



Evelyn Deceuninck
CEO

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE DICHIARAZIONE DI CONFORMITA / DECLARATION OF CONFORMITY

Name und Adresse der Firma

Nom et adresse de l'entreprise

Nome e indirizzo della ditta

Name and address of the firm



Airex AG

Industrie Nord 26

5643 Sins | Switzerland



3A Composites GmbH

Kiefernweg 10

49090 Osnabrück | Germany

CHRN: CHRN-MF-20000028

SRN: CH-MF-000014202

SRN: DE-AR-000013431

Wir erklären in alleiniger Verantwortung, dass die nachfolgend aufgelisteten Medizinprodukte / Nous déclarons sous notre propre responsabilité que les dispositifs médicaux listés ci-dessous / Dichiariamo sotto nostra responsabilità che i dispositivi medici elencati di seguito / We declare under our sole responsibility that the following listed medical devices

Artikelbezeichnung / Description **Gymnastikmatten /** Tapis d'exercice / Tappetini per esercizi / Exercise mats
de l'article / Descrizione dell'oggetto
/ Article description

Basis-UDI-DI / UDI-DI de base /
Global Model Number

7613005140S50YT

GMDN: 44417 **EMDN:** Z120603

das Medizinprodukt

le dispositif médical

il dispositivo medico

the medical device

Atlas, Aqua 140, Corona 200, Corona 185, Coronella 200, Coronella 185,
Coronella 120, Coronita, Diana, Hercules, Heritage, Fitline Studio, Fitline 140,
Fitline 180, Fitline 200, Fitness 120, Pilates 190, Titania, Xtrema

der Klasse / de la classe /
della classe / of class

Klasse I / de classe I / di classe I / classification I



allen grundlegenden Sicherheits- und Leistungsanforderungen der Medizinprodukteverordnung (EU) 2017/745 (MDR), Anhang VIII, Kap. III, Regel 1 entsprechen, die anwendbar sind / remplit toutes les exigences de la directive sur les dispositifs médicaux (EU) 2017/745 (MDR), Annexe VIII, chap. III, règle 1 qui le concernent / soddisfa tutte le disposizioni della direttiva (EU) 2017/745 (MDR), Allegato VIII, cap. III, regola 1 che lo riguardano / meets all the basic requirements of the medical device regulation (EU) 2017/745 (MDR), Annex VIII, cap. III, rule 1 which apply to it.

Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente - (EU) Medical Device Regulatory 2017/745 (MDR)
- DIN EN ISO 9001: 2015

Normes harmonisées, normes nationales et autres documents normatifs appliqués - DIN EN ISO 14001: 2015
- SN ISO 45001: 2018
Norme armonizzate o nazionali applicate, altri documenti normativi applicati - EN ISO 15223-1: 2021
- ISO 10993-10: 2021
Applied harmonized standards, national standards or other normative documents - ISO 20417: 2021

Konformitätsbewertungsverfahren

Procédure d'évaluation de la conformité

Procedimenti di valutazione della conformità

Conformity assessment procedure

(EU) 2017/745 (MDR), Anhang II & Anhang III

(EU) 2017/745 (MDR), Annexe II & Annexe III

(EU) 2017/745 Allegato II & Allegato III

(EU) 2017/745, Annex II & Annex III

Diese Konformitätserklärung ist bis zum **31.03.2027** gültig bzw. bis zur Ausstellung einer revidierten Konformitätserklärung nach Änderung des Produkts / This declaration of conformity is valid until **March 31, 2027** or until a revised declaration of conformity is issued after the product has been changed.

Airex AG
Industrie Nord 26
CH-5643 Sins



Sins, den 05.04.2024

i. A. Massimo Santarossa, QHSE Manager / PRRC



Airex AG
Speciality Foams
Industrie Nord 26
5643 Sins, Schweiz
Tel +41 41 789 66 00
Fax +41 41 789 66 60
www.3AComposites.com

Konformitätserklärung / Declaration de Conformité / Declaration of Conformity / Dichiarazione di Conformita

Wir / Nous / We / Noi

Name + Adresse der Firma

Nom + adresse de l'entreprise

Name + address of the company

Nome + indirizzo della ditta

**Airex AG
Speciality Foams
Industrie Nord 26
CH-5643 Sins**

erklären in alleiniger Verantwortung, dass / déclarons sous notre propre responsabilité que /
declare on our own responsibility that / dichiariamo sotto propria responsabilità che

das Medizinprodukt
le dispositif médical
the medical device
il dispositivo medico

**Balance products:
AIREX 34.55
Balance-pad, Balance-pad Elite,
Balance-pad XLarge, Balance-beam,
Balance-wedge XL**

Bezeichnung / nom / name / nome: Typ oder Modell
type ou modèle / type or model / tipo o modello

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG (od. 90/385/EWG), Klasse 1,
entspricht. / remplit toutes les exigences de la directive sur les dispositifs médicaux
93/42/CEE (ou 90/385/CEE), class 1, qui le concernent. / meet all the provisions of the
directive 93/42/EEC (or 90/385/ECC), class 1, which apply to him. / adempie a tutte de
exigenze della direttiva 93/42/CEE (oppure 90/385/CEE), classe 1, che lo riguardano.


Angewandte harmonisierte oder
nationale Normen
Normes harmonisées ou
appliquées nationales
Applied harmonized or
national norms
Norme armonizzate o
nazionale applicate

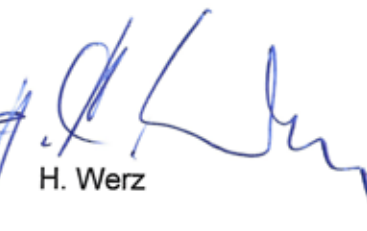
- **RCC Study No. A39284/Nov 2005:
AIREX S34.55 Balance products
Primary Skin Irritation Study in Rabbits**
- **RCC Study No. 802732
AIREX S34.55 Balance products
Contact Hypersensitivity in
Albino Guinea Pigs**
- **Determination of antifungal properties
acc. To SN 195 921**
- **Determination of antibacterial properties
Acc. To SN 195 920**

Konformitäts-Bewertungs-Verfahren
Procédure d'évaluation de la conformité
Conformity assessment procedures
Procedimento d'evaluazione della
conformita

**93/42/EWG, Anhang 7
93/42/CEE, annexe 7
93/42/ECC, annex 7
93/42/CEE, allegato 7**

Sins, 03. April 2013
Ort, Datum / lieu, date
place, date / luogo, data


Dietmar Rakutt


H. Werz



TRADE MARKS:

GYMNIC
The Way to Move

FIT-BALL



Ledraplastic
spa

www.gymnic.com

E-mail: info@gymnic.com

P.E.C.: ledraplastic@postacerta.net

CAPITALE SOCIALE € 516.000 i.v.

33010 OSOPPO (UD) Italia - Via Brigata Re, 1

Tel. +39-0432-975051 - Fax +39-0432-975788

Cod. Fisc. / Part. IVA IT 00161320304 (TVA-VAT-MWS)

Reg. Imp. UD NR. 00161320304

C.C.I.A.A. Udine REA n. 85305 M. UD001249

Banks:

BANCA ANTONVENETA SPA fil. OSOPPO (UD)

IBAN IT 17 N 05040 64010 000001174536

SWIFT ANT BIT 2P 89B

OSOPPO, LI 26.06.2013

VS. RIF.

NS. RIF. NC/lm

DA CITARE NELLA RISPOSTA

CHINESPORT SPA
Via Croazia, 2
33100 UDINE

To whom it may concern

We, LEDRAPLASTIC SPA – Via Brigata Re, 1 – 33010 OSOPPO (UD) – ITALY (firm registration number: UD – 85305), hereby declare that our products are MADE IN ITALY, tested and that:

- They are conform to the European norm nr. 2009/48/EC (safety of toys)
- They are conform to the REACH regulation on banned phthalates (Directive nr. EC 1907/2006)
- They are LATEX free
- They are CE marked

We remain at your disposal for any further information.

Yours faithfully,

LEDRAPLASTIC S.P.A.
Nevio Cosani



TRADE MARKS:

GYMNIC
The Way to Move

FIT-BALL

ROBY

Ledraplastic

spa

www.gymnic.com

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Nevio Cosani