

DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY KONFORMITÄTSERKLÄRUNG

CE

Modello/Model/Modell: **OW04 STEP**

Famiglia di prodotti/Product Family/Produktfamilie: **P03** BASIC UDI-DI: **805071407P03CZ**

Descrizione: **CALZATURE PREDISPOSTE PER INSERIMENTO ORTESI-TUTORE**

Description: **PRE-SET ORTHOTIC SHOES**

Beschreibung: **ORTHESENSCHUHE FÜR KINDER**

duna SRL

IN QUALITÀ DI FABBRICANTE DICHIARA E GARANTISCE che questo prodotto

- è classificato come Dispositivo Medico non invasivo di Classe I secondo quanto previsto dalle regole dell'Allegato VIII del Regolamento (UE) 2017/745 relativo ai dispositivi medici;
- appartiene alla classe CND Y063303 "calzature ortopediche di serie";
- è conforme ai requisiti essenziali e alle disposizioni del Regolamento (UE) 2017/745 relativo ai dispositivi medici.

AS MANUFACTURER DECLARES AND GRANTS THAT this product

- Is registered as non-invasive Medical Devices of 1st Class according to the rules specified in the attachment VIII of EU Regulations 2017/745 of medical devices;
- belongs to the class "orthopaedic shoes ready-made";
- conforms to the essential requirements and appliances of the EU regulation 2017/745 regarding medical devices

ALS HERSTELLER ERKLÄRT UND GARANTIERT diese Produkt

- Es wird gemäß den Bestimmungen von Anhang VIII der Verordnung (EU) 2017/745 über Medizinprodukte als nicht-invasives Medizinprodukt der Klasse I eingestuft.
- gehört zur CND-Klasse Y063303 "Orthopädisches Standardschuhwerk".
- entspricht den grundlegenden Anforderungen und Bestimmungen der Verordnung (EU) 2017/745 in Bezug auf Medizinprodukte.

DATA / DATE / DATUM

2021/06/14

- CEO -



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duna[®]
ORTHOPAEDIC SHOES INDUSTRY

ENG

Dear Customer,
we thank you for choosing Duna's therapeutic shoes.

Duna is leader in the production of healthy, therapeutic and orthopaedic pre-set shoes, which gather the best result of our long-lasting experience and competence in the field of orthopaedic shoes.

Duna has always succeeded in matching our anatomical and biomechanical competence with the aesthetic appeal of a very fashion and avant-garde product.

We remind you that the correct use of a 1st Class medical device such as pre-set orthopaedic shoes is important to reach the therapeutic effect for which it is born.

USE

Duna shoes are made of first-choice materials, leather and high-end tech materials, accessories and natural and anti-allergic tested fabrics according to EU appliances for sale purposes.

The qualitative degree of the materials used enables the feet to breath correctly and avoids hyper-sensibility risks. No substance release is possible except in the case of lining in particular colours or of excessive foot sweating. Materials are treated with a sanitization process which avoids any damage to the feet in case of unexpected release of colour (beyond the mere colouring of the socks).

It is always a common rule to frequently change the type of shoes worn and leave them far from heat spots in order to let them dry naturally.

It is absolutely necessary to wear the shoes with socks especially in the case of use of therapeutic or personalized insoles. Cases of excessive foot reddening together with other types of unforeseen occurrences due to the combination of Duna shoes with other medical devices such as insoles, orthoses, etc., must be shown to the orthopaedic technician or to the retailer during the phase of revision, test or functional shoe-restoring.

Shoes must be completely unfastened to enable the foot to enter the shoe correctly and avoid any irregular stretching of the materials, which might damage the shoes and compromise the integrity of the product.

The personalized insole must be taken out of the shoes every day and dried apart when it is not used.

Duna shoes are designed to be worn with insoles, whether including those provided with the shoes or personalized insoles, in order to achieve the required therapeutic effect. The shoes must be used regularly and not used for extraordinary activities that might cause excessive consumption.

Duna is not responsible for damages of the product and caused to people due to the improper use of the shoes.

Duna reserves the right to evaluate any complain and any relative occurrence before making a decision about the case in question.

The average life of Duna shoes is about 6 months if they are correctly used.

Here below you can find the list of icons also reported in the label of the shoe box, which grants the product's traceability. The present flyer together with the original shoe box showing the shoe label must be kept to identify the production lot and shown in case of complain.

MAINTENANCE

A basic rule for long-lasting shoes is to clean them properly. A wrong or occasional maintenance of the shoes is the first reason of their excessive consumption.

In case of wrong or superficial cleaning or maintenance Duna is not responsible for any damage that might occur.

Duna shoes must be cleaned and brushed carefully and, only when necessary, washed with a slightly wet sponge and a small quantity of neutral soap. Once dried, they can be brushed and polished after having applied a specific leather-moisturizing cream.

Suede leather must be brushed and cleaned with a slightly wet sponge. Once dried, they must be brushed all over the upper.

The heel and the outsole of the shoes should be periodically checked by an orthopaedic technician to avoid an excessive consumption and grant the right walking gait.



I CLASS - MEDICAL DEVICE REGULATIONS (EU)
2017/745 Instruction for use Rev. 1 del 16/01/2023

LABEL SYMBOLS LEGEND



Instruction for use inside



Medical Device



Family of medical device



Fabrication Date (Year-Month-Day)



Manufacturer



Serial Number



Unique Device Identifier