duna
ORTHOPAEDIC SHOES INDUSTRY

INFINITE SOLUZIONI

ENDLESS SOLUTIONS

DECLARATION OF CONFORMITY ACCORDING TO THE NEW EUROPEAN REGULATION 2017/45 REGARDING MEDICAL DEVICES

Dear Customer,

we hereby inform you that DUNA orthopaedic shoes are nowadays placed in the market by using the CE certification in appliance with the European Regulation 2017/475 regarding Medical Devices, commonly known as MDR, which replaces the old European Directive 93/42/CEE from May 26th, 2021.

The new European Regulation is born at the aim of granting more and more product safety, traceability, and efficiency to the final end user-customer.
DUNA has further taken the occasion of the introduction of the new regulation as a new challenge to improve its own production processes and final products.

In order to grant the conformity of its own products according to the new MDR, since the beginning of 2020 DUNA has been proceeding to certify the Quality Management System in accordance with the ISO13485:2016 standard specifications concerning Medical Devices, and during the last months DUNA has also proceeded to grant the single product traceability according to UDI system requirements listed in the new regulation.

Each regular-fitting model placed into the market by DUNA is identified with a UDI-DI unique code both in the European Database of medical devices (EUDAMED) and in the international market. This code is added to the Serial Number used to identify each model in the production process inside the factory.

According to the new MDR requirements regarding the information provided with the medical devices, you will find some news about the label applied on the shoe box and about the user's manual included inside each shoe box.

In the label you will find some icons to simplify the product/device identification, whose description is included in the legend inside the user's manual, and the manufacturing date of the shoes. This is given in addition to the information already supplied for the shoe identification and traceability by means of the Serial Number.

In addition to the User's Manual, which has been revised to satisfy the requirements of the new regulation, you will find the CE Declaration of Conformity, where the article's name and its belonging family of medical devices are reported, including the Basic UDI-DI code and its description.

As mentioned in the User's Manual, in case of complain it is absolutely necessary and compulsory to keep the Certification of Conformity and the original shoes box with its own label.

All the efforts that have been made during this difficult period to fulfil the requirements of the new European Regulation 2017/745 belong to our mental behaviour that has always brought our company to grant an absolutely high-quality product, which is manufactured according to safety, traceability and efficiency rules that must be applied to any medical device.

Yours faithfully,

Chief of the Technical Dept.
Quality and Innovation Technology
Ing. Paolo Bellelli
(in charge of the MDR regulation for Product market placing)

Chief of Sale and Product Development Manager
Maurizio Rosiglioni
(in charge of the MDR regulation for after-sale)

Falconara M.ma, May 26th, 2021