

THE FIRST SAFETY SHOE FOR THE
DIABETIC FOOT



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SALUBER[®]

Safety diab

USER

INFO SHEET

 **CERTIFIED MEDICAL DEVICE**

CE

SAFETY AND OCCUPATIONAL FOOTWEAR

USER INFO SHEET

Read carefully these instructions before using

Safety footwear is considered Personal Protective Equipment (PPE). The CE marking indicates that the product satisfies the basic health and safety requirements of the Regulation (EU) 2016/425 (annex II). The footwear has been approved by notified body N.0498 (Ricotest srl, Via Tione 9 – 37010 Pastrengo VR – Italy - www.ricotest.com) and classified as II Category

The EU Declaration of Conformity is available at the following address <https://saluber.com/declaratio-nofconformity/>

RECOMMENDED USE AND LIMITS OF USE

The law considers the employer responsible for all that concerns the suitability of the PPE for the type of risk present (characteristics of the PPE and category to which it belongs). Before using check that the characteristics of the chosen model correspond to your requirements for use. Do not use the footwear for any other purpose not referred to in this Informative Note.

SALUBER safety shoes are suitable for the following protections: impact and/o crushing of the toetips, slipping, mechanical aggression of the surface. The product is indicated for the following uses: industry, metalworking, civil construction, agriculture, stores, trucks and cranes etc.

The correct interpretation of symbols and classes marked on the product help to choose the suitable PPE according to the risk involved as indicated here below:

- impact and/o crushing of the toetips: all the footwear certified according to EN ISO 20345;
- impact shock of the heel against the ground: footwear carrying the following symbols: SB-E, S1-S2-S3, OB-E, O1-O2-O3
- slipping: all footwear
- cold: footwear carrying the symbol CI
- heat: footwear carrying the symbol HI
- water: footwear carrying the symbol WRU (waterproof upper) or WR (water resistant)
- hot contact of the outsole: footwear carrying the symbol HRO
- static electricity charges: footwear carrying the symbols A, S1-S2-S3, O1-O2-O3
- ankle bone impact: AN
- resistance to penetration of the sole: footwear carrying the symbols SB-P, S1-P, S3, OB-P, O1-P, O3
- resistance to oils Hydrocarbons: footwear carrying the symbols FO, S1, S2, S3
- other risks according to any specific additional symbol

Please inform the manufacturer SALUBER SRL and the local competent Authority of any serious incident related to the device.

SALUBER safety footwear is not suitable for protection against risks not referred to in this Informative Note and in particular those covered by III^o category personal protection equipment as defined in the Regulation (EU) 2016/425.

CE MARKING

The product is designed and manufactured in conformity with the basic health and safety requirements

of the Regulation (EU) 2016/425 for Personal Protective Equipment of second-category and with the basic and additional (optional) requirements for safety footwear according to EN ISO 20347:2012 standards or with the basic and additional (optional) requirements for safety footwear according to EN ISO 20345:2011 standard.

As well as the mandatory basic requirements envisaged by standard EN ISO 20345:2011 or standard EN ISO 20347:2012 SALUBER safety footwear meets also requirements which may be recognized by by means of symbols or by indicating the respective categories visibly marked on the bellows or on the tongue.

MARKING on the bellows/tongue (example):

| | |
|---------------------------------------|---|
| Manufacturer (logo) | SALUBER SRL |
| Address | Via M.te Verena, 31 - Cassola (VI) - Italia |
| Shoe size | 42 EUR |
| Name of article | Safety Diab |
| Conformity marking | CE |
| Reference standard | EN ISO 20345:2011 |
| Symbol and protection category | S3SRA |
| Batch (month and year of manufacture) | LOT mm/yy/000 |
| Country of manufacture | Made in Serbia |

CE marking indicates that the product satisfies the essential requirements envisaged by Regulation (EU) 2016/425 for personal protective equipment such as harmlessness to health, ergonomic and comfort, solidity and sturdiness of the product, protection against the risks listed in this informative note.

MATERIALS AND MANUFACTURING

All materials used – both natural or synthetic – as well as the applied processing techniques, have been chosen to meet the requirements expressed by the European technical standards in terms of safety, ergonomics, comfort, solidity and innocuousness.

BASIC AND ADDITIONAL REQUIREMENTS

Class I: footwear in leather and other materials, excluding all-rubber or all-polymeric footwear

Protection symbols

Symbol (s) indicating the protection provided and/or, where applicable, the appropriate class.

| | |
|----|--|
| SB | Basic requirements for safety footwear (with toe-cap "200J") |
| OB | Basic requirements for occupational footwear |

Alongside with the envisaged by the Standard, other characteristics may be necessary for both safety and occupational footwear. Additional requirements for special applications are marked with Symbols (see tab 1) and/or categories (see tab 2). The categories are the most common combinations of basic and additional requirements.

Tab.1

| Symbol | Requirements/Specifications | Required performance |
|--------|----------------------------------|----------------------|
| P | Perforation resistance | ≥ 1100 N |
| E | Energy absorption of seat region | ≥ 20 J |

| <i>Symbol</i> | <i>Requirements/Specifications</i> | <i>Required performance</i> |
|---------------|---|-----------------------------|
| A | Antistatic footwear | 0.1 ÷ 1000 MΩ |
| C | Conductive footwear | < 0.1 MΩ |
| WRU | Water penetration and absorption of upper | ≥ 60 min. |
| CI | Cold insulation of sole complex | At -17° C |
| HI | Heat insulation of sole complex | At 150° C |
| HRO | Resistance to hot contact of the outsole | At 300° C |
| FO | Resistance of sole to fuel oil | ≤ 12 % |
| WR | Water resistant footwear | ≤ 3 cm ² |
| M | Metatarsal protection (for EN ISO 20345 only) | ≥ 40 mm (EU size 41/42) |
| AN | Ankle protection | ≤ 10 kN |
| CR | Cut resistance of the upper (for EN ISO 20345 only) | ≥ 2,5 (index) |

Categoria di protezione fornita

Tab. 2

| | |
|----|--------------------------------------|
| S1 | SB + closed seat region + A + E + FO |
| S2 | S1 + WRU |
| S3 | S2 + P + cleated outsole |
| O1 | OB + closed seat region + A + E |
| O2 | O1 + WRU |
| O3 | O2 + P + cleated outsole |

Slip resistance symbols

| | | | |
|-----|---|-----------|-----------|
| SRA | Surface: ceramic tile floor | Heel slip | min. 0,28 |
| | Lubricant: water and detergent solution | Flat slip | min. 0,32 |
| SRB | Surface: smooth steel | Heel slip | min. 0,13 |
| | Lubricant: glycerol | Flat slip | min. 0,18 |
| SRC | SRA + SRB | | |

WARNINGS

This footwear maintains the indicated safety requirements only if correctly worn and in good conditions. Before using carefully check conditions and cleanliness; make sure the product is suitable for your use and try it on (select the right size). Replace the footwear in case it is clearly worn or damaged (unstitching, cracks, excessive wear of the outsole etc). The manufacturer declines all responsibilities for any damage and/or consequences resulting from improper use of the footwear.

If the shoe is declared to be equipped with toe-cap and anti-perforation insert, check their presence before use.

The penetration resistance of this footwear has been measured in laboratory using a truncated nail of diameter of 4,5 mm and a force of 1100 N (about 112Kgs). Higher forces or nails of smaller diameter will increase the risk of penetration occurring. In such circumstances alternative preventative measures should be considered. Two generic types of penetration resistant inserts are currently available in PPE footwear: metal types and non-metal materials. Both types meet the minimum requirements for penetration resistance of the standard marked on this footwear but each type has different additional advantages or disadvantages including the following:

- Metal insert: the risk is less affected by the shape of the sharp object (i.e. diameter, geometry, sharpness) but, due to shoemaking limitations, it does not cover the entire area of the shoe.
- Non-metal insert: may be lighter, more flexible and provide greater coverage area when compared with

metal, but penetration resistance may vary more depending on the shape of the sharp object (i.e. diameter, geometry, sharpness).

The choice should be based on risk assessment related to real working conditions. For more information about the type of penetration resistant insert provided in your footwear please contact the manufacturer or supplier detailed on these instructions.

Please note that no footwear can guarantee a total protection from all possible impacts or penetrations

The maximum grip of the sole is generally reached after certain "running-in" of the footwear (comparable to car tyres) for removing silicone residue and release agents, and any other physical and/or chemical surface irregularities. The slip resistance can also change depending on the sole wear; to satisfy the specifications does not guarantee in any case the absence of slipping in any condition.

CLEANING AND MAINTENANCE

- New footwear coming from its original box is generally ready for use
- Choose the model suitable for your specific work and environmental protection requirements
- Choose the right size, preferably by trying the shoe on
- Do not wash under running water
- Do not use solvents and other aggressive detergents to clean
- Clean with a damp cloth and to remove stains use soft brushes and cloths dampened in warm water
- Use specific products for cleaning and maintaining leather

STORAGE AND PRODUCT SHELF LIFE

To prevent the risk of deterioration, safety footwear must be carried and stored in its original packaging, in dry and not too hot places

When stored under normal conditions (light, temperature, and relative humidity) the obsolescence of a footwear is generally estimated in:

- 10 years after the date of manufacturing for shoes with upper leather, rubber and thermoplastic materials (such as SEBS etc) and EVA
- 5 years after the date of manufacturing for shoes including PVC
- 3 years after the date of manufacturing for shoe including PU and TPU

REMOVABLE INSOLE

If the footwear is equipped with a removable insole, the certified ergonomic and protective functions refer to the whole footwear (including the insole). Always use the footwear with its insole in place! Replace the insole only with an equivalent model from the same original supplier.

Safety footwear without removable insoles must be used without insole, because its introduction could adversely affect the protective functions.

DISPOSAL

The product lifetime is strictly related to its use, cleaning cycles, and consequent material degradation. At the end of useful life be sure to not leave the product in the natural environment: please follow your local environmental regulations and properly dispose of it. Further information regarding these regulations can be obtained from your local authorities.

ANTISTATIC FOOTWEAR

Antistatic footwear should be used if it is necessary to minimize electrostatic build-up by dissipating electrostatic charges thus avoiding the risk of spark ignition of, for example, flammable substances and vapours, and if the risk of electric shock from any electrical apparatus or live parts has not been completely eliminated. It should be noted, however, that antistatic footwear can not guarantee an adequate protection against electric shock as it introduces only a resistance between foot and floor. If the risk of electric shock has not been completely eliminated, additional measures to avoid this risk are essential. Such measures, as well as, the additional tests mentioned below, should be a routine part of the accident prevention program at the workplace

Experience has shown that, for antistatic purposes, the discharge path through a product should normally have an electrical resistance of less than 1000 M Ω at any time throughout its useful life. A value of 100 K Ω is specified as the lowest limit resistance of a product when new, in order to ensure some limited protection against dangerous electric shock or ignition in the event of any electrical apparatus becoming defective when operating at voltages of up to 250 V. However, under certain conditions, users should be aware that the footwear might give inadequate protection and additional provisions to protect the wearer should be taken at all times. The electrical resistance of this type of footwear can be changed significantly by flexing, contamination or moisture. This footwear will not perform its intended function if worn in wet conditions. It is therefore necessary to ensure that the product is capable of fulfilling its designed function of dissipating electrostatic charges and also of giving some protection during the whole of its lifetime. The user is recommended to establish an in-house test for electrical resistance and use it at regular and frequent intervals. If worn for prolonged periods and in moist and wet conditions, class I footwear can absorb moisture and become conductive. If the footwear is worn in conditions where the sole material becomes contaminated, wearers should always check the electrical properties of the footwear before entering a hazard area.

Where antistatic footwear is in use, the resistance of flooring should be such that it does not invalidate the protection provided by the footwear. In use no insulating elements should be introduced between the inner sole of the footwear and the foot of the wearer. If any insert is put between the inner sole and the foot, the combination footwear/insert should be checked for its electrical properties.

MEDICAL DEVICE

USER INFO SHEET

Read carefully these instructions before using

The product is a class I device for diabetic people with diabetic foot not-at-risk, at risk or at-very-high-risk. The product is indicated for primary and secondary prevention of diabetic foot. Please contact a specialist before using the product.










USE AND LIMITATIONS

Saluber orthopedic footwear is a medical device class I designed for diabetic people complicated by neuropathy or diabetic foot without active lesions or presenting anatomical or functional alterations of the foot and/or of the ankle.

Saluber orthopedic footwear are indicated also for rheumatic arthritis, other deformities or arthrosis.

CE MARKING AND SYMBOLS

Designed and produced in compliance with the safety requirements of the Regulation (EU) 2017/745

| | | | | | | | | |
|--|---|---|---|---|---|---|---|---|
|  |  |  |  |  |  |  |  |  |
| Made in + Country | Keep away from heat | Keep away from humidity | Read Instruction for use | Month/year/batch N. mm/aa/000 | Model | Medical Device | Manufacturer | Contains biological material of animal origin (lupper in leather) |

WARNINGS

For hygienic and therapeutic reasons do not exchange the footwear and/or the insole with other people.

Keep the footwear and its insole away from pets

The footwear and its insole should not come in contact with healthy skin and strictly not in contact with unhealthy skin (scratches, ulcers, wounds etc)

We recommend the use of stocking/socks.

If damaged or worn out the footwear and/or the insole should be replaced; please contact a specialist before buying a new footwear and/or insole.

The product is equipped with either a standard or a customized insole. Do not use the footwear if any of these insoles have been removed.

CLEANING THE INSOLE

For a longer use and a better hygiene we recommend to regularly clean the footwear and the insole using a damp cloth or a wet soft brush. Keep the product in dry places and do not expose the product to heat sources in general

For all the components of the product:

- Do not use alcoholic and corrosive liquids, detergents, alcohol, laundry detergents, bleach, ammonia and solvents.
- Do not use abrasive materials and/or products, brushes, steel wool, glass paper, blades or similar to remove stains or residues.
- Do not machine wash
- Do not soak the product

- Clean the lower lateral surface of the outsole using soft sponges dampened in warm water not exceeding 30°C and neutral soap.

At the time of purchase the footwear is equipped with a removable standard insole (SFDI - SFDH) or alternatively with a semi-customized orthotic (SFDJ) that has to be personalized by a technician to obtain a device that fulfil all the requirements for the treatment of the patient/client.

The insoles have the EN ISO 20345:2011 certification and satisfy the test requirements that indicate the maximum forefoot thickness as it follows:

SFDI 5,58 mm

SFDH 3,60 mm

SFDJ 4,75 mm

To guarantee the antistatic requirement, the footwear has been designed and produced with a conductive bridge. Therefore the product does not need an antistatic insock.

HOW TO INSERT THE INSOLE

Pay particular attention when inserting the insole and make sure you open the footwear and gently slide the insole in until it perfectly fits the shoe.

It is important not to change the structure of the footwear and of the insole so as not to alter the product performance.