

# **Safety toe cap in an orthopaedic work shoe**

## **Safety shoe**

An orthopaedic work shoe in which a safety toe cap is placed is legally defined as an orthopaedic safety shoe. After all, the purpose of the safety toe cap is to protect the user of the orthopaedic safety shoe from certain health and safety risks. Users of orthopaedic safety footwear are mostly patients. An extremely vulnerable target group with a (seriously) increased risk of permanent injury in foot accidents.

**An orthopaedic safety shoe must comply with current European legislation Regulation EU/2016/425 for Personal Protective Equipment (PPE).** This PPE legislation requires the orthopaedic safety shoe manufacturer to demonstrate that the orthopaedic safety shoe, as personal protective equipment, meets all essential health and safety requirements. Under this PPE legislation, the last person to make a modification to the orthopaedic safety shoe is considered as manufacturer of the orthopaedic safety shoe.

An accredited European test institute assesses, among other things, by means of tests whether the orthopaedic safety shoe fully complies with **the corresponding standard EN-ISO 20345**, which specifies how an orthopaedic safety shoe meets all essential health and safety requirements. After successful completion of the tests and other procedures, the orthopaedic safety shoe is certified by an accredited body ("Notified Body").

An orthopaedic safety shoe must always be legally certified in accordance with the current standard EN-ISO 20345 and the manufacturer of the orthopaedic safety shoe is fully product liable. A certified orthopaedic safety shoe must always carry the CE mark by law. The declaration of conformity and user manual must be supplied to the user of the orthopaedic safety shoe.

## **Safety toe cap**

A safety toe cap can basically be made of any material. Usually steel, aluminium, fibreglass or composite material are used. The manufacturer of the safety toe cap is obliged to demonstrate that this safety toe cap meets the legal requirements of standard EN- ISO 22568 for safety toe caps. The manufacturer of the safety toe cap is considered to be the person who last modified the safety toe cap.

An accredited European test institute assesses whether the safety toe cap fully complies with the EN-ISO 22568 standard. After approval, the safety to cap is certified by an accredited body ("Notified Body").

**A safety toe cap must always be certified in accordance with the current standard EN-ISO 22568 and carry a CE mark by law.** The declaration of conformity and user manual must be supplied to the purchaser of the safety toe cap. The manufacturer of the safety toe cap is fully product liable if the safety toe cap is used correctly.

The aforementioned legal obligations for safety toe caps also fully apply to a:

- **Safety toe cap of own manufacture:** Especially in the orthopaedic industry, it is common for a safety toe cap to be made by the orthopaedic shoemaker.
- **Safety toe cap from supplier:** The orthopaedic industry can purchase safety toe caps from suppliers.

**An orthopaedic safety shoe in which a certified safety toe cap is placed in accordance with the EN-ISO 22568 standard is always required to be certified in accordance with the EN-ISO 20345 standard for safety footwear by law.**

## **Supervisor**

Regulation EU/2016/425 for Personal Protective Equipment (PPE) with associated standard EN-ISO 20345:2022 for safety footwear is harmonised European legislation applicable in all European countries. **Each EU country has appointed a supervisor who monitors the application of European legislation Regulation (EU) 2016/425 and associated standard EN-ISO 20345:2022.**

For example, in the Netherlands, the supervisor is the Dutch Labour Inspectorate. National supervisors are coordinated and instructed on European legislation at European level, so that there is always a unified European enforcement policy.

Based on PPE legislation, the supervisor therefore checks whether products placed on the market comply with this legislation. In case of an accident, the supervisor will analyse what caused it, assess whether a violation has occurred and, in the latter case, hold the offender liable and, if necessary, impose sanctions. Market participants are obliged to report (suspected) unsafe products placed on the market to the Labour Inspectorate.

## **Orthopaedic work- and safety shoe**

Based on the above, the following **legal rules apply in Europe for an orthopaedic work and safety shoe:**

1. An orthopaedic work shoe in which a safety toe cap is placed is an orthopaedic safety shoe. An orthopaedic work shoe without a safety toe cap is an orthopaedic work shoe;
2. Both an orthopaedic work shoe and an orthopaedic safety shoe must comply with current European legislation Regulation EU/2016/425 for Personal Protective Equipment (PPE);
3. An orthopaedic safety shoe must be certified in accordance with the current standard EN-ISO 20345 and an orthopaedic work shoe without a safety toe cap must be certified in accordance with the current standard EN-ISO 20347;
4. In a certified orthopaedic safety shoe, the use of a safety toe cap certified in accordance with the current EN-ISO 22568 standard is required by law. This certified safety toe cap must be tested and approved in combination with the orthopaedic safety shoe in accordance with the current EN-ISO 20345 standard, after which it is a certified orthopaedic safety shoe;
5. Every orthopaedic work or safety shoe must always carry the CE mark by law. The declaration of conformity and user manual must be supplied to the user together with the orthopaedic work or safety shoe;

6. The points described above apply to any orthopaedic work and safety shoe, whether manufactured in-house or supplied by a supplier;
7. The manufacturer of an orthopaedic work or safety shoe is the last person to make a modification. The manufacturer of the orthopaedic work or safety shoe is always fully responsible and product liable by operation of law;
8. The person who markets an orthopaedic work or safety shoe without the legally required certification (and thus possibly an unsafe product) deliberately violates the law. The person is personally liable and punishable.

## **Conclusion**

**Marketing an orthopaedic work or safety shoe that is not certified as PPE is strictly prohibited (punishable) and must be reported to the supervisor.** This orthopaedic work or safety shoe is potentially unsafe and could endanger a patient. Using design, aesthetics or price as an argument to market an unsafe product is unacceptable. After all, health and safety are the most important conditions for a patient. An extremely vulnerable target group with a (seriously) increased risk of permanent injury in case of accidents.

*Author: Mr Jan Dirksen*

*The author Mr Jan Dirksen is the chairman of the NEN standards committee 'Foot- and Leg protection' of which he has been a member since 2014. In addition, Mr Dirksen has been a member of the European standards committee CEN TC/161 and the Global standards committee ISO TC/94 since 2019. The NEN committee is responsible for Dutch input on ISO standards related to foot and leg protection. The protocol relating to safety toe caps in a safety shoe in standard EN-ISO 20345:2022 was created mainly through the orthopaedic input of Mr Jan Dirksen*