

Replacing insoles in safety footwear

Safety footwear

A safety shoe must comply with the current European legislation Regulation EU/2016/425 for Personal Protective Equipment (PPE). This PPE legislation obliges the safety shoe manufacturer to prove that the safety shoe, as personal protective equipment, meets all essential health and safety requirements.

The current associated standard EN-ISO 20345 stipulates which essential health and safety requirements a safety shoe must meet. An accredited European test institute assesses whether the safety shoe fully complies with this standard EN-ISO 20345 and after approval, the safety shoe is certified by an accredited body ('Notified Body').

Insole in safety footwear

The manufacturer of a safety shoe is obliged, based on the current standard EN-ISO 20345 to construct a safety shoe and have it certified in combination with an interchangeable insole or non-interchangeable insole. This safety shoe may be placed on the market after certification by the footwear manufacturer. Ownership of the safety shoe is transferred to the buyer from the moment of sale by the manufacturer.

Replacing insoles in safety footwear

In case the original interchangeable insole in a safety shoe is replaced by an alternative insole, the new combination (safety shoe + alternative insole) must be re-tested as a change based on the current standard. This new current standard EN-ISO 20345:2022 has replaced and expired the old standard EN-ISO 20345:2011. The expired standard can therefore no longer be applied to demonstrate the essential requirements of the combination (safety shoe + alternative insole). Accredited test institutes therefore always test this combination based on the current standard EN-ISO 20345:2022.

The new current standard EN-ISO 20345:2022 stipulates that only in the case of an interchangeable insole in a safety shoe, it is allowed to replace the original interchangeable insole in the safety shoe with an alternative insole.

Replacing the original insole with an alternative insole is permitted according to this current standard EN-ISO 20345:2022 (section 8.3) by:

- **Safety shoe manufacturer:** provided that this safety footwear manufacturer has certified the alternative insole in combination with this safety shoe. After certification of the combination, the safety shoe manufacturer can:
 - a. Release the alternative insole on the market for use in this safety shoe;
 - b. Publish a manufacturing protocol for the alternative insole used in this safety shoe.

- **Manufacturer of the alternative insole:** provided that this insole manufacturer has had the alternative insole tested in combination with the original safety shoe based on the established protocol in EN-ISO 20345:2022. After approval of the tests, the alternative insole manufacturer may:
 - a. Release the alternative insole on the market for use in this safety shoe;
 - b. Publish a manufacturing protocol for the alternative insole used in this safety shoe.

Product liability and warranty

The manufacturer of (the protocol for) the alternative insole is product liable for the alternative insole in combination with the safety shoe. It should be noted that the person who manufactured the alternative insole based on a protocol must have followed the instruction from this protocol exactly. Including the mandatory registration of the alternative insole in combination with the original safety shoe. The purpose of this is to check whether the relevant combination (original safety shoe + alternative insole) has been tested and approved in accordance with standard EN-ISO 20345. In case the protocol for the alternative insole is not fully followed, the person who manufactured the alternative insole becomes the manufacturer of the new combination (original safety shoe + alternative insole). For this manufacturer of the new combination, all legal obligations apply to the safety shoe in accordance with PPE legislation, including product liability.

The manufacturer of the original safety shoe always remains product liable for this safety shoe. The manufacturer of the safety shoe cannot withdraw its product liability and warranty on the safety shoe, after the installation of an alternative insole by a third party, by operation of law.

Manufacturers who nevertheless withdraw their product liability and warranty on the original safety shoe, in case the original insole has been replaced by an alternative insole from a insole manufacturer, deliberately mislead their customers, employers and employees. These manufacturers ultimately disadvantage the users (mostly patients) for whom the orthopaedic insoles are medically necessary.

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 assess the cause: the alternative insole in the safety shoe and/or the original safety shoe.

Conclusion

The current standard EN-ISO 20345:2022 stipulates that the manufacturer of an alternative insole may also replace the insole in the original safety shoe. This manufacturer of an alternative insole can therefore be a different manufacturer from the manufacturer of the original safety shoe!

The manufacturer of the alternative insole may therefore replace the insole with its own alternative insole without the permission of the footwear manufacturer, provided that the safety shoe and alternative insole combination has been tested and approved in accordance with the current standard EN-ISO 20345:2022.

Based on European legislation, the supervisor has confirmed in writing that the safety shoe manufacturer always remains product liable for the original safety shoe.

The manufacturer of (the protocol for) the alternative insole is product liable for this combination (original safety shoe + alternative insole).

Thus, the manufacturer of the original safety shoe cannot, by operation of law, revoke its product liability and warranty after third-party installation of an alternative insole. Manufacturers and their industry associations that make such (threatening) statements deliberately mislead their customers, employers and employees with this misinformation. Patients for whom orthopaedic insoles are medically necessary are severely disadvantaged in this way.

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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 insoles in standard EN-ISO 20345:2022 was created mainly through the orthopaedic input of Mr Jan Dirksen