CHANGING INSOLES
IN WORK AND SAFETY FOOTWEAR (PROTECTIVE FOOTWEAR)

1. Protective footwear is personal protective equipment within the meaning of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE Regulation). Protective footwear must be subject to a conformity assessment procedure in accordance with the PPE Regulation. The manufacturer of protective footwear is responsible to ensure that the footwear complies with the applicable essential health and safety requirements of the PPE Regulation.

2. As part of the conformity assessment procedure, an accredited body (Notified Body) examines and tests whether protective footwear meets the applicable requirements of the PPE Regulation. A Notified Body carries out a so-called EU type-examination and subsequently issues an EU type approval (known as the 'certificate'). The examination and testing covers the entire protective footwear, including the insoles.

3. (Harmonized) standards explain how the applicable essential health and safety requirements of the PPE Regulation can be met. The applicable harmonized European standard is ISO 20345:2022 for safety footwear and ISO 20347:2022 for safety footwear without protective toecap. In practice, therefore, a manufacturer can design and manufacture protective footwear in accordance with these harmonized standards to ensure that the protective footwear is deemed to comply with the applicable legal requirements of the PPE Regulation.

Changing insoles in protective footwear

4. Replacing an insole in protective footwear is generally considered to be a modification of the protective footwear within the meaning of the PPE Regulation. The party inserting the new insole into the protective footwear would, as a result of this modification, acquire specific responsibilities under the PPE Regulation, namely as the manufacturer of the new combination of protective footwear and insole. The modifying party would therefore, among other things, be required to carry out a new conformity assessment procedure for the new combination of protective footwear and insoles.

5. Inserting a new insole is not considered to be a modification within the meaning of the PPE Regulation of the insole is manufactured in accordance (conformity) with:

   1) a manufacturer's protocol

   or

   2) Annex A of ISO 20345:2022 / ISO 20347:2022

   In this case, there is no modification to the protective footwear and therefore no new conformity assessment procedure under the PPE Regulation is required for the new combination of protective footwear and insoles. Both options are explained in more detail

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below.

1- Insoles according to a manufacturer's protocol

6. It has been common practice and accepted by the market for many years for manufactures of protective footwear to develop protocols containing specifications for insoles which can be used in that manufacturer's protective footwear without the need for a new conformity assessment procedure including certification (the EU type approval) under the PPE Regulation.

7. The manufacturer of the protective footwear has in fact examined the new combination of the protective footwear with the insole during the conformity assessment procedure (EU type-examination) already. The use of the new insole fabricated in accordance with such a protocol of a manufacturer of protective footwear has thus been taken into account by the Notified Body when conducting the EU type examination and is therefore part of the EU type approval (certification). Therefore, the use of an insole in conformity with the protocol of the manufacturer does not require a new conformity assessment or specifically a new EU type approval. This is because the use of an insole that complies with the manufacturer's protocol is already included and certified in the conformity assessment carried out by the manufacturer and the EU type approval applies to such new combination as well. There is no discussion about this in the market.

8. Therefore, third parties can also manufacture insoles in compliance with the PPE Regulation for this manufacturer's protective footwear based on these protocols. The use of insoles in accordance with the protocol does not constitute a modification of the protective footwear within the meaning of the PPE Regulation. Consequently, no new conformity assessment procedure is required. The conformity assessment carried out by the manufacturer of the protective footwear, including the protocol and the existing declaration of conformity of that manufacturer of the protective footwear, will continue to apply.

9. The manufacturer of the interchangeable insole, who has manufactured and supplied the insole in accordance with the protocol of the manufacturer of the protective footwear, does not have to carry out a new conformity assessment or to draw up a new declaration of conformity for the combination of the protective footwear and the interchangeable insole. When applying the safety footwear manufacturer's protocol, no party in the market has requested that a new conformity assessment is to be carried out.

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2 - Insoles according to Annex A of ISO 20345:2022 / ISO 20347:2022

10. The harmonized standards ISO 20345:2022 / ISO 20347:2022 specifically specify the handling of a (semi-)orthopedic insole in safety footwear and safety footwear without protective toecap in accordance with the PPE Regulation. Section 8.3 of these standards states that:

> **8.3 Insocks**
>
> If the footwear is supplied with a removable insock, it should be made clear in the leaflet that testing was carried out with the insock in place. A warning shall be given that the footwear shall only be used with the insock in place and that the insock shall only be replaced by a comparable insock supplied by the original footwear manufacturer or supplied by an insocks manufacturer which will supply insocks that fulfil the properties of this standard in combination with the foreseen safety footwear.

11. These harmonized standards allow Neskrid to offer a 4Allbrands insole in accordance with the PPE Regulation for another manufacturer's protective footwear without requiring the consent of the manufacturer of the protective footwear.

12. A 4Allbrands insole meets the specifications and requirements of ISO 20345:2022 or ISO 20347:2022 and has been tested accordingly by an accredited testing institute. The combination of a 4Allbrands insole with specific protective footwear has also been tested for compliance with the PPE Regulation and specifically ISO 20345:2022 or ISO 20347:2022.

13. The use of a 4Allbrands insole does, therefore, not constitute a modification of the protective footwear and does not require a new conformity assessment. The person who inserts a 4Allbrands insole into protective footwear in accordance with Neskrid's instructions does not thereby acquire any responsibilities as a manufacturer under the PPE Regulation.

14. This is because the use of a 4Allbrands insole has already been examined and certified by the manufacturer of the protective footwear using the harmonized standards ISO 20345:2022 or ISO 20347:2022. Annex A of the ISO 20345:2022 and ISO 20347:2022 standards provides specifications for the interchangeable insole that can be used in protective footwear designed and certified according to these standards. For example, Annex A of these harmonized standards specifies requirements for electrical properties, heat/cold insulation and toe protection in combination with safety footwear.

Annexes A of ISO 20345:2022 and ISO 20347:2022 are therefore (legally) identical to the use of manufacturers' protocols.

15. In fact, manufacturers of protective footwear have already incorporated the requirements of Annex A of ISO 20345:2022 or ISO 20347:2022 into the conformity assessment procedure, specifically in the EU type examination and EU type approval. The use of a 4Allbrands insole is therefore covered by the EU type approval, or certification to ISO 20345:2022 or ISO 20347:2022, carried out by the Notified Body appointed by the manufacturer of the protective footwear under the PPE Regulation. Therefore, the use of a 4Allbrands insole in combination with protective footwear in accordance with ISO 20345:2022 or ISO 20347:2022 does not constitute a modification of the protective footwear within the meaning of the PPE Regulation.

A 4Allbrands insole can therefore be used in conformity with the PPE Regulation with any model of protective footwear provided that:

a. the protective footwear is certified by the manufacturer of this protective footwear in accordance with the standards ISO 20345:2022 or ISO 20347:2022, and
b. the 4Allbrands insole has been tested by Neskrid in combination with the protective footwear in accordance with the standards ISO 20345:2022 or ISO 20347:2022

In these cases, no new or additional conformity assessment or a new declaration of conformity in accordance with the PPE Regulation is required, but the EU type approval and the manufacturer's declaration of conformity continue to apply.

Insoles are not personal protective equipment

16. Furthermore, an insole itself does not fall within the definition of personal protective equipment under the PPE Regulation. Article 3(1)(a) of the PPE Regulation defines personal protective equipment as follows:

> *equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;*

17. An insole is not worn or held by a person to protect against certain risks.

18. An insole is also not an interchangeable component of personal protective equipment within the meaning of Article 3(1)(b) of the PPE Regulation, as an insole is not essential for the protective function of safety footwear.

19. The guide to the PPE Regulation in its version dated 23 October 2024 confirms this view. It states that an interchangeable component is a part that is used exclusively in this personal protective equipment. As an insole is not used exclusively in safety footwear, the definition of an interchangeable component within the meaning of Article 3(1)(b) of the PPE Regulation is not met.

20. The replaceable insole itself is also not essential for the protective function of the safety footwear and is therefore not an interchangeable component for an item of equipment within the meaning of Article 3(1)(b) of the PPE Regulation.

21. In addition, Neskrid is not the manufacturer of the safety footwear. Therefore, Neskrid cannot issue a declaration of conformity for the safety footwear or the combination of safety footwear and a 4Allbrands insole in accordance with the PPE Regulation.

(Semi-)orthopaedic insole is a medical device

22. However, a (semi-)orthopaedic insole is considered to be a medical device within the meaning of the European Medical Device Regulation (EU) 2017/745 (MDR). A (semi-)orthopaedic insole from 4Allbrands is covered by the MDR and fulfils the requirements of the MDR. Neskrid, as the manufacturer of the 4Allbrands (semi-)orthopaedic insole, issues a declaration of conformity in accordance with the MDR, in the form of:

a. of a certificate for a customised orthopaedic insole or orthopaedic shoe.
b. a declaration of conformity for series-produced (semi-)orthopaedic insoles

Conclusion and summary

23. A 4Allbrands insole from Neskrid that has been tested in combination with safety footwear according to the standards ISO 20345:2022 for safety footwear or ISO 20347:2022 for work footwear without safety toe cap and meets these requirements can be used in the corresponding safety footwear in conformity with the PPE Regulation without the need for a new or additional conformity assessment, specifically a new EU type examination or type approval, or a new declaration of conformity.

24. The competent Dutch inspectorate (*Arbeidsinspectie*) and the German Bayerische Gewerbeaufsicht have already confirmed the working method of Neskrid with regard to the (semi-)orthopaedic insoles of 4Allbrands. Neskrid's publications and the list of possible combinations of safety shoes with 4Allbrands insoles that have been tested by Neskrid can be found on the following websites:

www.neskrid.com and www.4allbrands.eu

25. The most important points of this background document can be summarised as follows:

1) Responsibilities of the manufacturer:

- The manufacturer of safety footwear is responsible for compliance with the basic health and safety requirements for safety footwear set out in the PPE Regulation.
- In accordance with the PPE Regulation, safety footwear must undergo a conformity assessment in which a notified body carries out an EU type examination and issues an EU type approval (certification).

2) Use of a interchangeable insoles:

- The starting point is that changing an insole in safety footwear constitutes a significant modification within the meaning of the PPE Regulation.
- The person or party inserting the new insole assumes responsibility for the new combination of safety footwear and insole as the manufacturer and must carry out a new conformity procedure based on this modification, unless the insole complies with the protocol of the original manufacturer of the safety footwear or Annex A of the harmonised standards ISO 20345:2022 for safety footwear and ISO 20347:2022 for safety footwear without a toe cap.

3) Protocol of the manufacturer:

- Safety footwear manufacturers can create their own protocol for insoles that can be used in their safety footwear without the need for a new conformity procedure.

- The use of an insole in conformity with a protocol is then already included by the manufacturer of the safety footwear or the Notified Body in the EU type examination and EU type approval (certification), so that the use of such insoles is already certified. A new conformity assessment and/or declaration of conformity is therefore not required.

4) Compliance with ISO standards:

- The harmonised standards ISO 20345:2022 and ISO 20347:2022 specify how to handle a (semi-)orthopaedic insole in safety shoes and safety shoes without toecaps.
- The use of an insole that complies with Annex A of ISO standard 20345:2022 or ISO standard 20347:2022 is included in the EU type examination and the EU type approval (certification) of the safety footwear manufacturer certified according to these standards, so that the use of such insoles is also already certified (similar to the protocols of the safety footwear manufacturers). A new declaration of conformity is therefore not required.
- 4Allbrands insoles from Neskrid have been manufactured in accordance with these standards and tested by an accredited testing institute in combination with safety footwear.

5) Legal status of replaceable insoles:

- A replaceable insole is not considered personal protective equipment within the meaning of the PPE Regulation, as it is not worn or held by a person to protect against certain risks.
- An insole is also not a replaceable component with a protective function of personal protective equipment.

6) Medical device:

- A (semi-)orthopaedic insole from 4Allbrands is a medical device within the meaning of the European Medical Device Regulation (EU) 2017/745 (MDR) and complies with the MDR regulation.
- Within the framework of the MDR regulation, Neskrid, as the manufacturer of the (semi-)orthopaedic 4Allbrands insole, issues either a certificate for a customised orthopaedic insole or a declaration of conformity for a series-produced (semi-)orthopaedic insole.