

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE EC DECLARATION OF CONFORMITY

I enlighet med Annex IV -Förordning 2017/1745 om medicintekniska produkter
According to Annex IV - Regulation 2017/1745 on medical devices.

Tillverkare / Manufacturer

Embreis AB

Adress/ Address

Tumstocksvägen 11 B
187 66 Täby
Sverige/ Sweden

SRN

SE-MF-000003023

PRODUKT IDENTIFIKATION/ DEVICE IDENTIFICATION

Produktkategori/ Product Category

Prosthetic Leg Covers

Basic UDI

73401896371QY

Klassifikation/ Classification

Klass I (Regel 1, 4.1, bilaga VIII)
Class I (Rule 1, 4.1 annex VIII)

Avsedd användning/ Intended purpose

Ge protesben och protesfot ett mer kosmetiskt och naturligt utseende.
Give the prosthetic leg and foot a more cosmetic and lifelike appearance.

Produktnamn/ Name of the device

- eSkin Leg Cover
- eSkin Foot Cover

Artikelnummer/ Part number

Se bilaga 1 och 2/ See appendix 1 and 2

Vi intygar härmed under vårt eget ansvar att ovanstående medicintekniska produkt(er) uppfyller de tillämpliga kraven i EU-förordning 2017/1745 om medicintekniska produkter.

We hereby declare under our sole responsibility that the medical device(s) specified above meet the provision of the EU Regulation MDR 2017/1745 for medical devices.

Standards Applied

ISO 22523:2006 External limb prostheses and external orthoses- Requirements and test methods
ISO 14971:2019 Medical devices—Application of risk management to medical devices
ISO 13485:2016 Medical devices -- Quality management systems.

Ort och datum/ Place and date

Namnteckning/ Signature

Henrietta Z Hammarlund

Regulatory & Quality Manager

Bilaga 1/ Appendix 1

Artikelnummer/ Part number	Benämning/ Product name
E6S	eSkin Leg Cover Standard Toe
E6T	eSkin Leg Cover Split Toe
E6F	eSkin Foot Cover

Nr	Beskrivning	Beskrivning 2	UDI-DI
E6F2122L01	eSkin Foot Cover	Left, Size 21-22, Color 01	07340189639350
E6F2122L02	eSkin Foot Cover	Left, Size 21-22, Color 02	07340189638650
E6F2122L03	eSkin Foot Cover	Left, Size 21-22, Color 03	07340189639367
E6F2122L04	eSkin Foot Cover	Left, Size 21-22, Color 04	07340189639374
E6F2122L05	eSkin Foot Cover	Left, Size 21-22, Color 05	07340189639381
E6F2122L06	eSkin Foot Cover	Left, Size 21-22, Color 06	07340189639398
E6F2122L07	eSkin Foot Cover	Left, Size 21-22, Color 07	07340189639565
E6F2122L08	eSkin Foot Cover	Left, Size 21-22, Color 08	07340189639572
E6F2122L09	eSkin Foot Cover	Left, Size 21-22, Color 09	07340189639589
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E6T2122L02	eSkin Leg Cover Split Toe	Left, Size 21-22, Color 02	07340189639008
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The following documents were signed Friday, April 11, 2025



EU-DOC-371QY-Benkosmetik.pdf
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Signatures

4/11/2025 2:29:30 PM (CET)



S Henrietta Zetterström Hammarlund, QA

henrietta.zetterstrom@embreis.com
Signed with electronic ID (BankID)



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About this receipt

This document has been electronically signed using Assently E-Sign in accordance with eIDAS, Regulation (EU) No 910/2014 of the European Parliament and of the Council. An electronic signature shall not be denied legal effect and admissibility as evidence in legal proceedings solely on the grounds that it is in an electronic form or that it does not meet the requirements for qualified electronic signatures. A qualified electronic signature shall have the equivalent legal effect of a handwritten signature. Assently E-Sign is provided by Assently AB, company registration number 556828-8442. Assently AB's Information Security Management System is certified according to ISO/IEC 27001:2013.