

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE EC DECLARATION OF CONFORMITY

I enlighet med Annex IV -Förordning 20171745 om medicintekniska produkter
According to Annex IV - Regulation 20171745 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 Cosmetic Gloves

Basic UDI

73401896361QV

Klassifikation/ Classification

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

Avsedd användning/ Intended purpose

Ge protesarm och hand ett mer kosmetiskt och naturligt utseende.
Give the prosthetic arm and hand a more cosmetic and lifelike appearance.

Produktnamn/ Name of the device

- eSkin Cosmetic - Natural Glove
- eSkin Cosmetic - Standard Glove
- eSkin MYO - Natural Glove
- eSkin MYO - Standard Glove
- eSkin Mechanical - Natural Glove
- eSkin Mechanical - Standard Glove

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 2017/745 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 2017/745 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

Stockholm 2024-06-14

Namnteckning/ Signature

Henrietta Z Hammarlund

Regulatory & Quality Manager

Bilaga 1/ Appendix 1

Artikelnummer/ Part number	Benämning/ Product name
E44N	eSkin Cosmetic Natural Male
E44S	eSkin Cosmetic Standard Male
E45N	eSkin Cosmetic Natural Female
E45S	eSkin Cosmetic Standard Female
E43N	eSkin Cosmetic Natural Child
E43S	eSkin Cosmetic Standard Child
E41N	eSkin Mechanical Natural Female
E41S	eSkin Mechanical Standard Female
E42N	eSkin Mechanical Natural Male
E42S	eSkin Mechanical Standard Male
E46N	eSkin MYO Natural Male
E46S	eSkin MYO Standard Male
E47N	eSkin MYO Natural Female
E47S	eSkin MYO Standard Female
E48N	eSkin MYO Natural Child
E48S	eSkin MYO Standard Child