

EU Konformitätserklärung

Document number: **D000012193**
 Document Owner: **Marija Pesic**
 Document CoOwner: **Regulatory Affairs Manager**
 Classification: **Regulatory Compliance**
 Document Language:
 From Template: **D000000100 EU Konformitätserklärung Rev: 04**
 Project Number: **PJ-00000135**
 Project Name: **Skeo Sealing Liner TF-conical (PIP)**
 Regulatory Required: **Yes**
 Revision: **00**
 Effective Date: **2024-01-25**

Release List

Type	Number	Title	State	Revision Number	Release Date	Released By	Reviewed By
Express DCO	DCO-00004479	Freigabe Konformitätserklärung	Released	00	2024-01-25	Dominik Schmidt	

Change details

Number	Change Reason	Description
DCO-00004479	Freigabe Konformitätserklärung	

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EU-Konformitätserklärung EU Declaration of Conformity

Der Unterzeichner, der den nachstehenden Hersteller vertritt,
The signatory, who represents the below-mentioned manufacturer,

Hersteller / Manufacturer

Ottobock SE & Co. KGaA
Max-Näder-Str. 15
37115 Duderstadt, Germany

SRN: DE-MF-000010487

erklärt hiermit in alleiniger Verantwortung, dass das Produkt
herewith declares under his sole responsibility that the product

Produkt / Product

6Y111=*

Skeo Sealing 3D
Risikoklasse I
gemäß Verordnung (EU) 2017/745
Basis-UDI-DI (GMN):
4032767000000006Y1113S

Skeo Sealing 3D
Risk class I
according to Regulation (EU) 2017/745
Basic UDI-DI (GMN):
4032767000000006Y1113S

in folgenden Varianten
in the following variants

Varianten / Variants

6Y111=250x10
6Y111=250x17
6Y111=265x10
6Y111=265x17
6Y111=280X10
6Y111=280X17
6Y111=300X10

6Y111=300X17
6Y111=320X10
6Y111=320X17
6Y111=340X10
6Y111=340X17
6Y111=360X10
6Y111=360X17

6Y111=380X10
6Y111=380X17
6Y111=400X10
6Y111=400X17
6Y111=450X10
6Y111=450X17

mit seiner Zweckbestimmung
with its intended purpose

Zweckbestimmung / Intended purpose

Das Produkt ist ausschließlich für die exoprothetische Versorgung der
unteren Extremität einzusetzen.

The product is intended exclusively for lower limb exoprosthesis fittings.

mit den Bestimmungen der nachstehenden EU-Verordnung(en), EU-Richtlinie(n) und Gemeinsame Spezifikation(en) übereinstimmt.
is in conformity with the relevant provisions of below-mentioned EC Regulation(s), EC Directive(s) and Common Specification(s).

2017/745 EU Verordnung des Europäischen Parlaments und des Rates über Medizinprodukte
Regulation of the European Parliament and of the Council on medical devices

Die Konformität wird erklärt nach Artikel 52(7), Anhang II und III der Verordnung (EU) 2017/745.
The conformity is declared based on Article 52(7), Annex II and III of the Regulation (EU) 2017/745.

Duderstadt, 2024-01-25

Ort, Datum / Place, Date

DocuSigned by:

8E9C930BDF39427

Arne Jörn
Geschäftsführer
Managing Director

DocuSigned by:

585E7E892648454...

Dominik Schmidt
Für die Einhaltung der Regulierungsvorschriften
verantwortliche Person
Person Responsible for Regulatory Compliance

Abschlusszertifikat

Umschlag-ID: 7701382338B543AABCBC1CDDDB34B1B3D	Status: Abgeschlossen
Betreff: Mit DocuSign abschließen: 20240125_EU_Konformitätserklärung.pdf	
Quellumschlag:	
Dokumentenseiten: 2	Signaturen: 2
Zertifikatsseiten: 5	Initialen: 0
Signatur mit Anleitung: Aktiviert	Umschlagelsteller:
Umschlag-ID-Stempel: Aktiviert	Marija Pesic
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien	Max Nader St. No. 15
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	IP-Adresse: 91.25.151.58

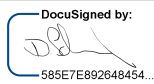
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Status: Original	Inhaber: Marija Pesic	Standort: DocuSign
25.01.2024 13:56:20	Marija.Pesic@ottobock.de	

Unterzeichnereignisse

Dominik Schmidt
 dominik.schmidt@ottobock.de
 Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)

Signatur



Signaturübernahme: Auf Gerät gezeichnet
 Mit IP-Adresse: 91.25.151.58

Zeitstempel

Gesendet: 25.01.2024 13:59:27
 Eingesehen: 25.01.2024 14:00:49
 Signiert: 25.01.2024 14:01:14

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:

Akzeptiert: 09.12.2021 16:55:32
 ID: eba79040-b78d-4107-ae1f-6d4b14c1fda7

Arne Jörn
 arne.joern@ottobock.de
 COO/CTO, Geschäftsführender Direktor
 Ottobock SE & Co. KGaA
 Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)



Signaturübernahme: Vorgegebener Stil
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Gesendet: 25.01.2024 14:01:16
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 Signiert: 25.01.2024 15:17:46

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 ID: 02773ebd-2e5e-4ef0-837e-46cfb60fbe59

Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel
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Zeugen-Ereignisse	Signatur	Zeitstempel
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Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	25.01.2024 13:59:27

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