

Declaration of Conformity

The signatory, who represents the below-mentioned manufacturer,

Manufacturer:

Ottobock SE & Co. KGaA
Max-Näder-Strasse 15
D-37115 Duderstadt

herewith declares that the products listed in appendix I are conform to the relevant provisions of the below-mentioned EC Directive.

93/42/EEC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Notified Body: N.A.

Notified Body Address: N.A.

Notified Body Number: N.A.

The conformity is declared based on Appendix VII of the Directive 93/42/EEC.

This declaration is valid for all products of the above design that are fabricated according to the respective fabrication documents.

Duderstadt 2018-04-03

Date

Management CTO

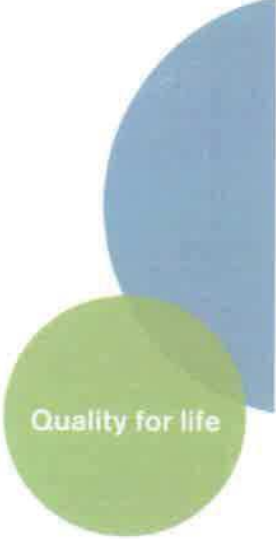
Dr. Andreas Goppelt

Chief Sales & Marketing
Officer (CSMO)

Ralf Stuch

Head of Regulatory Affairs

Dominik Schmidt



Quality for life

Herewith the Ottobock SE & Co. KGaA confirms for the listed products, their variants* and accessories: The assessment of the conformity (according Directive 93/42/EEC) is completely accomplished according to the applicable risk class. The correspondent technical documentation and EC declaration of conformity are maintained by the manufacturer and can be reviewed on request.

* The article number in combination with the product name enables a correlation to the main product. Variants means sizes and body side and are therefore constructed under the same conditions. The detail expression appears after the "equal" symbol of the main product code.

| UMDNS code | UMDNS term | DIMDI notification | Notification date |
|-------------|--|--|-------------------|
| 17-873 | Orthoses, Foot/Ankle | DE/CA08/3.1.20-02 | 31.07.2006 |
| Article No. | Product name (en) | Product name (de) | Country of Origin |
| 28U11 | Walk-On AFO | Walk On Unterschenkelorthese | CN |
| 28U22 | Walk On Flex | Walk On Flex | CN |
| 28U23 | WalkOn Trimable | WalkOn Trimable: Dynam. Unterschenkelorthese | CN |
| 28U24 | WalkOn Reaction | WalkOn Reaction | CN |
| 28U90 | Ankle Foot Orthosis | Unterschenkelorthese | DE |
| 50S1 | Dyna Ankle - Dynamic Ankle Orthosis | Dyna Ankle | DE |
| UMDNS code | UMDNS term | DIMDI notification | Notification date |
| 13-150 | Prostheses, Foot | DE/CA08/3.1.20-09 | 03.08.2006 |
| Article No. | Product name (en) | Product name (de) | Country of Origin |
| 1D10 | Dynamic foot with toes | Dynamic Fuß mit Zehen | DE |
| 1G9 | Pedilan Single Axis Foot, light | Pedilan-Normgelenk-Fuß, leicht | DE |
| 1H37 | Single Axis Foot/Ankle Men, 10mm, Toes | Normgelenk-Fuß mit Zehen | DE |
| 1H38 | Single Axis Foot Only Men | Normgelenk-Fuß mit Zehen | DE |
| 1S49 | SACH Foot | SACH-Fuß mit Zehen | DE |
| 1S90 | SACH FOOT | SACH-Fuß mit Zehen und abgespreizter Großzehe | DE |
| 1WR95 | Foot for water resistant prothesis | Fuß für wasserfeste Gehilfe | DE |
| UMDNS code | UMDNS term | DIMDI notification | Notification date |
| 13-158 | Prostheses, Joint | DE/CA08/3.1.20-11 | 03.08.2006 |
| Article No. | Product name (en) | Product name (de) | Country of Origin |
| 3R15 | Single Axis Knee Joint, Break | Modular-Bremskniegelenk, monozentrisch, mit Vorbringer und Schutzhülse | DE |
| 3R40 | Lightweight Knee Joint, Lock | Modular-Leichtkniegelenk, monozentrisch mit Feststellung | DE |
| 3R60 | Modular EBS Knee Joints | Modular-EBS-Kniegelenk, polyzentrisch, mit hydraulischer Schwunghasensteuerung | DE |
| 3R95 | Lightweight Hydraulic Knee | Modular-Kniegelenk, Hydraulik | DE |
| 7E4 | Modular Hip Joint -Free Motion- | Modular-Hüftgelenk, monozentrisch, mit Streckvorrichtung | DE |
| 7E5 | Modular Single Axis Hip Joint | Modular-Hüftgelenk, monozentrisch, mit Feststellung | DE |
| 7E7 | modular hip joint | Modular Hüftgelenk | DE |

| UMDNS code | UMDNS term | DIMDI notification | Notification date |
|--------------------|--|--|--------------------------|
| n.v. | not defined | DE/CA08/3.1.20-12 | 07.08.2006 |
| Article No. | Product name (en) | Product name (de) | Country of Origin |
| 6Y42 | Standard Pro | Standard Pro Liner | DE |
| 6Y70 | Silicon Gel Liner | Silicon Gel Liner | DE |
| 6Y80 | AK Adapt Liner | TF-Adapt-Liner | DE |
| 6Y90 | Copolymer liner with distal attachment | Otto Bock Copolymer Liner | DE |
| 6Y92 | Copolymer Liner without dist. attachment | Copolymer Liner ohne distalen Anschluß | DE |
| 6Y94 | DVS Liner | DVS Liner | DE |
| UMDNS code | UMDNS term | DIMDI notification | Notification date |
| n.v. | not defined | DE/CA08/3.1.20-14 | 07.08.2006 |
| Article No. | Product name (en) | Product name (de) | Country of Origin |
| 6R6 | Foam Cover | Schaumstoff-Überzug, PUR-Weichschaum | DE |
| UMDNS code | UMDNS term | DIMDI notification | Notification date |
| 13-160 | Prostheses, Leg | DE/CA08/3.1.20-33 | 16.07.2008 |
| Article No. | Product name (en) | Product name (de) | Country of Origin |
| 3K5 | Knee -Shin Component-Plastic | Knie-Waden-Pasteil | DE |
| 3P19 | Knee-Shin Component | Knie-Waden-Pasteil, einachsig | DE |
| 3P23 | JÜPA Knee-Shin Component | Jüpa-Knie-Waden-Paßteil | DE |
| 3R6 | Foam Cover (AK) | Schaumstoff-Überzug, PUR Weichschaum | DE |