

## Declaration for Materials and Substances

The signatory, who represents the below-mentioned manufacturer,

**Manufacturer:**

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

Herewith declares that the materials and substances in Annex I can be used for the fabrication of medical devices under consideration of their article-numbers, within the scope of the intended use listed below and under consideration of the usage instructions mentioned in the instruction for use.

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The manufacturer of medical devices is bound to choose materials and substances which are planned to be used in medical devices in a way that a toxic impact is excluded and by taking account of the intended purpose of the device an alternating compatibility of the used materials is given and demonstrated in an appropriate way (Annex I, chapter 7.1 of the directive 93/42/EWG).

After long-time period and permanent usage of these materials and substances, we do not know any occurrences which might hint to an unbearable risk using these materials and substances for the fabrication of prostheses and orthoses.

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**Valid through: 2020-04-02 (YYYY.MM.DD)**

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**

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Quality for life

## Annex I Materials and Substances

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

Article Number	Product Name	Intended use
170D21	Y Hook & Loop	Closures for orthoses or lap belts
170Z4	Hook & Loop Strap	Closures for orthoses or lap belts
21B16	Synthetic Bandage	Ready-made bandages
21B2	Traction Bandage	Ready-made bandages
21B21	Silesian Bandage	Ready-made bandages
21B33	Silesian Bandage, Modified	Ready-made bandages
21B37	Thigh Support Bandage	Ready-made bandages
21Y122	Hook & Loop Closure with strap guide loop	Closures for orthoses or lap belts
21Y78	Hook & Loop Closure with strap guide loop	Closures for orthoses or lap belts
22K10	Underarm Supports for Children	Walking and therapy aids
22K2	Underarm Supports	Walking and therapy aids
22K4	Underarm Supports	Walking and therapy aids
22K5	Underarm Supports for Children	Walking and therapy aids
22K8	Axillary Crutches	Walking and therapy aids
22S2	Support Cane	Walking and therapy aids
22S3	Support Cane	Walking and therapy aids
22S4	Support Cane	Walking and therapy aids
29Y57	Lamination Disk	Fabrication of sockets
501S16	Binding Head Screw	Fabrication of orthoses
519L5	Silicone Parting Agent	Fabrication of sockets
5Y7	Tubercle Seat	Paddings, fabrication of sockets
5Z15	Fibre Preform	Fabrication of sockets
5Z3	ThermoLyn® flexible	Fabrication of sockets
605P8	Light Metal Profile Bar	Fabrication of orthoses
605T1	Aluminium Sheet Metal	Fabrication of inserts and clamps
608T1	Brass Sheet	Fabrication of inserts and clamps
616G7	Moltoprene	Fabrication of orthoses
616S5	BetaSil	Silicone material intended to fill scars and depressions, creating padding in order to achieve a fully contoured fit between a standard silicone/gel liner and the residual limb
616S6	BetaSil	Silicone material intended to fill scars and depressions, creating padding in order to achieve a fully contoured fit between a standard silicone/gel liner and the residual limb
616T111	ThermoLyn® supra soft plus Silicone	Fabrication of high flexible prosthetic sockets in upper limb prostheses.

616T112	ThermoLyn supra flexible	Fabrication of sockets
616T113	ThermoLyn supra flexible	Fabrication of sockets
616T120	ThermoLyn® PP Copolymer	Positioning shells, seating shells, orthopaedic aids
616T16	ThermoLyn® RCH 1000	Positioning shells, seating shells, orthopaedic aids
616T169	ThermoLyn® soft	Fabrication of sockets
616T183	ThermoLyn® (PETG) clear	Fabrication of sockets
616T19	ThermoLyn® PE 200	Positioning shells, seating shells, orthopaedic aids
616T20	ThermoLyn® PP Homopolymer	Positioning shells, seating shells, orthopaedic aids
616T200	ThermoLyn® EVA/LDPE SilverShield®	Fabrication of sockets
616T22	ThermoLyn® RCH 500	Positioning shells, seating shells, orthopaedic aids
616T25	Padding Material, Self-Adhesive	Positioning shells, seating shells, orthopaedic aids
616T252	Antibacterial ThermoLyn® rigid	Fabrication of self-supporting check sockets (limited period of use) such as TT , TF and HD
616T253	Antibacterial ThermoLyn® soft	Fabrication of flexible prosthetic sockets in upper limb prostheses
616T269	Antibacterial ThermoLyn® soft	Fabrication of flexible prosthetic sockets in upper limb prostheses
616T283	Antibacterial ThermoLyn® clear	Fabrication of sockets
616T3	ThermoLyn® Trolene	Fabrication of orthoses
616T39	ThermoLyn® flexible	Positioning shells, seating shells, orthopaedic aids
616T4	Mipolam (consider plasticisers)	For the fabrication of sleeves for prostheses
616T420	Antibacterial ThermoLyn® PP-H	Fabrication of orthoses
616T44	ThermoLyn® RCH 500	Positioning shells, seating shells, orthopaedic aids
616T483	Antibacterial ThermoLyn® PETG clear	Fabrication of sockets
616T495	Antibacterial ThermoLyn® PE 200	Fabrication of orthoses
616T52	ThermoLyn® rigid	Fabrication of sockets
616T53	ThermoLyn® soft	Fabrication of sockets
616T58	ThermoLyn® PE 200	Positioning shells, seating shells, orthopaedic aids
616T59	ThermoLyn® supra soft	Fabrication of sockets
616T6	Trial Sheeting	Fabrication of trial shoes
616T60	ThermoLyn® PE 200	Positioning shells, seating shells, orthopaedic aids
616T61	ThermoLyn® PE 200	Positioning shells, seating shells, orthopaedic aids
616T69	ThermoLyn® soft	Fabrication of sockets
616T70	ThermoLyn® Europlex	Positioning shells, seating shells, orthopaedic aids
616T73	ThermoLyn® Pedilon	Positioning shells, seating shells, orthopaedic aids

616T83	ThermoLyn® (PETG) clear	Fabrication of sockets
616T92	Relax Foam	Fabrication of paddings
616T95	ThermoLyn® PE 200	Positioning shells, seating shells, orthopaedic aids
617H119	Orthocryl Lamination Resin 80:20 PRO	Fabrication of sockets
617H12	Pedilen Rigid Foam 200	Fabrication of paddings
617H17	Orthocryl®, Flexible	Fabrication of sockets
617H19	Orthocryl® Lamination Resin 80:20	Fabrication of sockets
617H21	Orthocryl® Sealing Resin	Fabrication of sockets
617H255	C-Orthocryl Sanitized	Fabrication of sockets
617H35	Pedilen® Flexible Foam 150	Paddings
617H4	Araldit® Lamination Resin	Fabrication of sockets
617H42	Pedilen® Flexible Foam 300	Paddings
617H43	Silicone Gel	Paddings, sockets
617H44	Silicone Gel	Paddings, sockets
617H46	Bonding Agent for Silicone	For the fabrication of sleeves for prostheses
617H51	Orthocryl®, Extra Flexible	Fabrication of sockets
617H55	C-Orthocryl®	Fabrication of sockets
617P14	Hardening Paste	Fabrication of sockets
617P15	Quick Hardener	Fabrication of sockets
617P21	Hardener for Pedilen® Hard Foams	<b>Fehler! Keine gültige Verknüpfung.</b>
617P3	Hardener	Fabrication of sockets
617P32	Hardener for Pedilen® Flexible Foams	Paddings
617P37	Hardening Powder	Fabrication of sockets
617R15	TP.C Carbon Fibre Woven	Fabrication of sockets
617S10	Neoprene	Fabrication of paddings
617S102	Biflex Sheet Material	Fabrication of paddings
617S119	Dyatec	Fabrication of paddings
617S12	Evazote	Fabrication of paddings
617S120	Dyasoft Sheet Material	Fabrication of paddings
617S13	Evazote	Fabrication of paddings
617S130	Superform	Fabrication of paddings
617S131	Superform	Fabrication of paddings
617S132	Superform	Fabrication of paddings
617S187	Nora® Lunatec Combi 7	Fabrication of paddings
617S14	Evazote	Fabrication of paddings
617S15	Neoprene	Fabrication of paddings
617S16	Plastazote	Fabrication of paddings
617S17	Plastazote	Fabrication of paddings
617S18	Plastazote	Fabrication of paddings

617S19	Sportolon	Fabrication of paddings
617S20	Sportolon	Fabrication of paddings
617S203	Pedilin® SilverShield®	Fabrication of paddings
617S21	Plastazote	Fabrication of paddings
617S229	Antimikrobielles Nora® Lunairmed®	Fabrication of paddings
617S191	Nora® Lunasoft SL	Fabrication of paddings
617S192	Nora® Lunasoft SLW	Fabrication of paddings
617S188	Nora® Lunairflex	Fabrication of paddings
617S190	Nora® Lunairflex perforated	Fabrication of paddings
617S181	Nora® Lunairmed	Fabrication of paddings
617S3	Pedilin®	Fabrication of paddings
617S180	Nora® Lunairmed perforated	Fabrication of paddings
617S189	Nora® Lunalastik	Fabrication of paddings
617S6	Plastazote	Fabrication of paddings
617S67	PPT	Fabrication of paddings
617S68	PPT	Fabrication of paddings
617S7	Plastazote	Fabrication of paddings
617S70	Dynoform	Fabrication of paddings
617S71	Dynoform	Fabrication of paddings
617S8	Plastazote	Fabrication of paddings
617S80	Superform, soft	Fabrication of paddings
617S81	Superform, soft	Fabrication of paddings
617S82	Superform, soft	Fabrication of paddings
617S83	Superform, soft	Fabrication of paddings
617S84	Superform, soft	Fabrication of paddings
617S85	Superform, soft	Fabrication of paddings
617S86	Superform, soft	Fabrication of paddings
617S9	Evazote	Fabrication of paddings
617S90	Dino Foam	Fabrication of paddings
617S91	Dino Foam	Fabrication of paddings
617S92	Multicolor OD	Fabrication of paddings
617S93	Dino Foam	Fabrication of paddings
617S94	Dino Foam	Fabrication of paddings
617W1	Versamide	Fabrication of sockets
617Z2	Resin Color Paste	Fabrication of sockets
617Z3	Resin Color Paste	Fabrication of sockets
617Z4	Resin Color Paste	Fabrication of sockets
617Z5	Resin Color Paste	Fabrication of sockets
617Z58	Resin Color Paste	Fabrication of sockets
617Z6	Resin Color Paste	Fabrication of sockets
617Z7	Resin Color Paste	Fabrication of sockets

617Z8	Microballoons, White	Fabrication of sockets
617Z9	Resin Color Paste	Fabrication of sockets
619M2	Rubber Padding	Paddings, fabrication of sockets
619M3	Rubber Padding	Paddings, fabrication of sockets
619M4	Rubber Padding	Paddings, fabrication of sockets
619M5	Cellular Unvulcanized Rubber	Paddings, fabrication of sockets
620P1	Pressed Cork	Paddings, fabrication of sockets
620P15	PS Velour	Fabrication of paddings
620P16	PS Velour	Fabrication of paddings
620P17	PS Velour	Fabrication of paddings
620P2	Flexible Cork	Paddings, fabrication of sockets
620P3	Rubber Cork	Paddings, fabrication of sockets
620P4	Microcork	Paddings, fabrication of sockets
621J2	Chrome Kid Leather	Linings and covers
621R1	Blank Calf Leather	Linings and covers
621R3	Chrome-Tanned Calf Leather	Straps
621R4	Orthopaedic Chrome-Tanned Leather	Straps
621R5	Vegetable-Tanned Calf Leather	Linings and covers
621S4	Plain Chamois Sheep Leather	Linings and covers
621W2	Milled Leather	Linings and covers
621X3	Helanca Double-Stretch Synthetic Leather	Linings and covers
623F62	SpaceTex® 3D-spacer fabric	Fabrication of paddings
623G1	Elastic Belt	Fabricaton of orthoses
623G3	Elastic Belt	Fabricaton of orthoses
623G4	Double Elastic Belt	Fabricaton of orthoses
623H14	Carrying Strap	Fabricaton of orthoses
623H2	Carrying Strap	Fabricaton of orthoses
623M8	Velvetone	Linings and covers
623P2	Terry Cloth Padding Fabric, Self-Adhesive	Paddings, fabrication of sockets
623P5	Padding Tape	Fabrication of paddings
623T1	Cotton Stockinette	Taking plaster casts
623T3	Perlon Stockinette, white	Taking plaster casts
623T9	Nylglass Stockinette, white	Taking plaster casts
623Z1	Hook & Loop Closure	Closures for orthoses or lap belts
623Z12	Hook & Loop Closure Strap	Closures for orthoses or lap belts
623Z2	Elastogrip Closure	Closures for orthoses or lap belts
623Z3	Hook & Loop Closure with strap guide loop	Closures for orthoses or lap belts
623Z37	Loop Strap	Closures for orthoses or lap belts
623Z40	Loop Strap	Closures for orthoses or lap belts

623Z5	Hook & Loop Hook Strap	Closures for orthoses or lap belts
623Z6	Hook & Loop Loop Strap	Closures for orthoses or lap belts
623Z7	Hook & Loop Loop Strap	Closures for orthoses or lap belts
623Z8	Hook & Loop Hook Strap	Closures for orthoses or lap belts
623Z9	Hook & Loop Closure	Closures for orthoses or lap belts
627B40	Polyethylene Tape 3M	Fabrication of sockets
633F23	Silicone Grease	Fabrication of sockets
633F50	Silicone Grease	For the fabrication of sleeves for prostheses
633T2	Separating Lubricant	Fabrication of sockets
634A1	Thinner and Solvent	Fabrication of sockets
634A28	Thinner	Fabrication of sockets
635L12	Orthocryl® Varnish	Fabrication of sockets
635L14	Orthocryl® Varnish	Fabrication of sockets
635L2	Special Varnish	Fabrication of sockets
635L8	Socket Interior Varnish	Fabrication of sockets
636K17	Lightweight Putty	Fabrication of sockets
636K40	Repositionable Spray Adhesive	Fabrication of sockets
636K41	Repositionable Spray Adhesive	Fabrication of sockets
636K6	Plastilin Clay	Preparing models
636K7	Orthocryl® Putty	Fabrication of sockets
636K9	Akemi Fast Curing Putty	Fabrication of sockets
636N9	Otto Bock Contact Adhesive	Adhering flexible materials
636W17	Plastic Adhesive	Fabrication of cosmetic covers
636W71	CP Contact Adhesive	Adhering flexible materials
639A1	Talcum Powder	Fabrication of sockets
640Z1	Silicoderm Skin Protection Cream	Taking plaster casts
640Z10	Cellona® Skin Protection Cream	Taking plaster casts
640Z5	Plaster Insulating Cream	Taking plaster casts
641T2	Body Protection Stockinette	Taking plaster casts
641T3	Body Protection Stockinette	Taking plaster casts
642V15	Impresil Silicone	Taking plaster casts
645C1	Copying Pen	Taking plaster casts
645C2	Grease Pen	Taking plaster casts
651P4	Nirosta Profile Bar	Fabrication of orthoses
651T1	Steel Sheet	Fabrication of inserts and clamps
699G1	Elastic Plaster Bandage	Taking plaster casts
699G19	Fast setting plaster Biplatrix	Fabrication of sockets
699G3	Cellona® Plaster Bandage	Taking plaster casts
699G30	Cellacast Xtra® Rigid Bandage	Taking plaster casts
699G9	Cellona® Plaster Bandage	Taking plaster casts
699S1	Pedilen® Impression Foam	Taking plaster casts

6T2	Pedilin Cone	Fabrication of sockets
81A1	Nylon Stocking on rolls	Fabrication of sockets
83N1	Maxoglu	Prosthesis and epithesis fixing system
83T4	Transpad	Orthosis and mask fixing system
85F1	Plaster Isolation Liquid (1 Liter)	Fabrication of sockets
85H11	Pastasil Silicone	Taking plaster casts, test prostheses
85H31	Kun-Gel Silicone	Fabrication of residual limb end bearing cushions and soft pads of silicone
85H7	Maxosil Silicone	Fabrication of maxillo-facial prostheses
85P11	Chlorosil Silicone	Fabrication of liners, orthoses, prostheses, and scar care products of silicone
85P21	Chlorosil Silicone	Fabrication of liners, orthoses, prostheses, and scar care products of silicone
85P31	Chlorosil Silicone	Fabrication of liners, orthoses, prostheses, and scar care products of silicone
85Z1	Pigmsil	For the fabrication of sleeves for prostheses
85Z2	Pigmsil	For the fabrication of sleeves for prostheses
85Z3	Pigmsil	For the fabrication of sleeves for prostheses
85Z4	Pigmsil	For the fabrication of sleeves for prostheses
85Z5	Pigmsil	For the fabrication of sleeves for prostheses
85Z6	Pigmsil	For the fabrication of sleeves for prostheses
85Z7	Pigmsil	For the fabrication of sleeves for prostheses
85Z8	Pigmsil	For the fabrication of sleeves for prostheses
87A1	Alignate Silicone	For the fabrication of sleeves for prostheses
87Z1	Fibersil	For the fabrication of sleeves for prostheses
87Z2	Fibersil	For the fabrication of sleeves for prostheses
87Z3	Fibersil	For the fabrication of sleeves for prostheses
87Z4	Fibersil	For the fabrication of sleeves for prostheses
87Z5	Fibersil	For the fabrication of sleeves for prostheses
87Z6	Fibersil	For the fabrication of sleeves for prostheses
87Z7	Fibersil	For the fabrication of sleeves for prostheses
88M10	Fixing Bandage	Mask fixing system
99B23	End Bearing Cushion	Residual limb bedding in the socket
99B26	Formable Distal Padding	Residual limb bedding in the socket
99B6	End Bearing Cushion	Residual limb bedding in the socket
OC1560	Easy-Proth® Anziehilfe	Fabrication of sockets, aids for resin technology