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Document owner(s)	Department, title	Date	Version
E. Masih	Biomechanical engineering, BSc	1-7-2024	1.2
G.J.M. Tuijthof	Biomechanical engineering, Prof	1-7-2024	1.2

Document release	Department, title	Date	Version
G.J.M. Tuijthof	Biomechanical engineering, Prof	Date	1.2

Document changes	Department, title	Date	Version	Summary of changes
E. Masih	Biomechanical engineering, BSc	26-3-2024	1.1	Doc setup
E. Masih	Biomechanical engineering, BSc	2-7-2024	1.2	Part off-the-shelf and custom made filled in
E. Masih	Biomechanical engineering, BSc	18-7-2024	1.2	Additional parts added
E. Masih	Biomechanical engineering, BSc	1-9-2024	1.2	Adjustments to prices and manufacturers
G.J.M. Tuijthof	Biomechanical engineering, Prof	4-8-2025	1.2	Final check and adjustments layout
				Adjustments to part names in alignment with CAD models and technical drawings;
G.J.M. Tuijthof	Biomechanical engineering, Prof	10-9-2025	1.2	addition risks

References

ISO 13485:2016        7.4, 7.5.8, 7.5.9, 7.6

Twente University

TechMed MDR Taskforce & Sustainable Healthcare Technology programme, GJM Tuijthof

Template name                Bill of Material

Template number            3.03.01.x

Template version            1.2

Template date                241004

Template change history

210928                Added criticality assessment sheet

241004                Added worksheet 'Template instructions', updated layout of worksheets



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Part Custom made components

Date2-7-2024 Part ID Custom-made Revision

Component ID	Component description	Revision	Revision date	Quantity	Units	Cost	Total cost	Manufacturer	Supplier/Distributor	Supplier ref	Validation/Verification	Risk assesment?
1.1.0	Ground plate assembly							NOTE: Manufacturer/Supplier are options			Verification	Risk3, Risk9, Risk10
3.02.3D Footplate_cross_large	Ground plate	5.0	22-6-2024	1	pieces	The costs are determined by supplying the .dxf of all components to be made from PP with the correct quantities per piece. A quotation is made by the supplier for this.	?	De laser frezer	De laser frezer	<a href="https://www.delaserfrezer.com/">https://www.delaserfrezer.com/</a>	Verification	No
3.02.3D Footplate_Side	Side	5.0	22-6-2024	2	pieces						Verification	No
3.02.3D Footplate_cross_small	Leg support	5.0	22-6-2024	1	pieces						Verification	No
3.02.3D Footplate_back	Back plate	5.0	22-6-2024	1	pieces						Verification	No
3.02.3D Footplate_Lock_new	Lock	5.0	22-6-2024	16	pieces						Verification	No
1.2.0	Footplate assembly										Verification	No
3.02.3D Footplate_Footplate	Footplate	2.0	1-7-2024	1	pieces						Verification	No
3.02.3D Footplate_Heel Support	Heel support	1.0	1-7-2024	1	pieces						Verification	No
3.02.3D Footplate_Heel lock	Heel locks	2.0	18-8-2024	3	pieces						Verification	No
1.3.0	3D printed components										Verification	Risk2, Risk 8, Risk9, Risk10
3D Footplate_Clamp_body	Telescopic clamp	1.0	16-5-2024	6	pieces	€ 2,93	?	Vormz	vormz.nl	<a href="#">Jouw 3D print service in Nederland   Vormz - 3D Print Service Nederland</a>	Verification	No
3D Footplate_Clamp lever	Telescopic lever	1.0	16-5-2024	6	pieces	€ 2,90	?	Vormz	vormz.nl	<a href="#">Jouw 3D print service in Nederland   Vormz - 3D Print Service Nederland</a>	Verification	No
3D Footplate_Clamp body enclosed_coup-tube	Connection clamp	2.0	17-5-2024	6	pieces	€ 2,38	?	Vormz	vormz.nl	<a href="#">Jouw 3D print service in Nederland   Vormz - 3D Print Service Nederland</a>	Verification	No



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Part Off-the-shelf components

Replace symbol 'A' with subsystem or system ID

Date2-7-2024 Part IDOff-the-shelf components Revision

Component ID	Component description	Revision	Revision date	Quantity	Units	Cost	Total cost	Manufacturer	Supplier/Distributor	Supplier ref	Validation/Verification	Risk assesment?
2.1.0	Rods										Verification	Risk9, Risk10
3D Footplate_Tube_large	Outer PMMA rod - Ø25-21mm	1.0	13-5-2024	6 * 175 mm	2 meter	€ 12,86	€ 12,86	Flexinplex Kunststoffe	Flexinplex Kunststoffen B	<a href="#">Plexiglas XT Buis Glashelder Ø 25x2MM L=2000MM   Flexinplex.nl</a>	Verification	No
3D Footplate_Tube_small	Inner PMMA rod - Ø20-16mm	1.0	13-5-2024	6 * 200 mm	2 meter	€ 11,91	€ 11,91	Flexinplex Kunststoffe	Flexinplex Kunststoffen B	<a href="#">Plexiglas XT Buis Glashelder Ø 20x2MM L=2000MM   Flexinplex.nl</a>	Verification	No
2.3.0	Remaining components										Verification	Risk9, Risk10
2.3.1	Ball-in-socket joint	1.0	1-5-2024	6	pieces	€ 2,06	€ 12,36	igus	igus	<a href="https://www.igus.nl/product/igubal-AGRM_AGLM_LC?artnr=AGLM08-LC">https://www.igus.nl/product/igubal-AGRM_AGLM_LC?artnr=AGLM08-LC</a>	Verification	No
2.3.2	Cardan	1.0	24-4-2024	6	pieces	€ 6,19	€ 37,14	Reely	Conrad	<a href="https://www.conrad.nl/nl/p/kunststof-universele-koppeling-reely-o-x-l-12-5-mm-x-33-mm-226467.html">https://www.conrad.nl/nl/p/kunststof-universele-koppeling-reely-o-x-l-12-5-mm-x-33-mm-226467.html</a>	Verification	No
2.3.3	Tube insertion cap	1.0	13-5-2024	6	pieces	€ 0,38	€ 1,88	Verpas B.V	Verpas B.V.	<a href="https://www.verpas.nl/insteekdoppen/rond-schroefdraad/pa-kunststof-schroefdraad/insteekbus-kunststof-draad-25-mm-m8-zwart/">https://www.verpas.nl/insteekdoppen/rond-schroefdraad/pa-kunststof-schroefdraad/insteekbus-kunststof-draad-25-mm-m8-zwart/</a>	Verification	No
2.3.4	Threaded insert	1.0	28-6-2024	6	pieces	€ 0,49	€ 48,61	RS	RS	<a href="https://nl.rs-online.com/web/p/threaded-inserts/0278578">https://nl.rs-online.com/web/p/threaded-inserts/0278578</a>	Verification	No
2.3.5	RVS screw M6x12mm	1.0	23-7-2024	6	pieces	€ 0,22	€ 1,32	Dresselhaus	Hornbach	<a href="https://www.hornbach.nl/p/dresselhaus-lenskopschroef-binnenzeskant-met-flens-m6x12-mm-iso-7380-galv-verzinkt-500-stuks/8699791/">https://www.hornbach.nl/p/dresselhaus-lenskopschroef-binnenzeskant-met-flens-m6x12-mm-iso-7380-galv-verzinkt-500-stuks/8699791/</a>	Verification	No
2.3.6	Bolt with a cross nut	1.0	16-5-2024	6	pieces	€ 0,70	€ 4,20	BAUHAUS	BAUHAUS	<a href="https://nl.bauhaus/stokschroeven/bout-met-dwarsmoer-gecentreerd/p/23515361">https://nl.bauhaus/stokschroeven/bout-met-dwarsmoer-gecentreerd/p/23515361</a>	Verification	No
2.3.7	RVS screw M6x40mm	1.0	18-8-2024	6	pieces	€ 0,13	€ 0,78	Dresselhaus	Hornbach	In-store availability	Verification	No
2.3.8	Nylon bolt M5	1.0	16-5-2024	6	pieces	€ 1,66	€ 10,00	Unknown	Bol.	<a href="https://www.bol.com/nl/nl/p/m5x25-metaalschroef-nylon-din-84/9300000132859377/?bltgh=s0kF3fQf7JoEdFOJKihPAg.2_13.14.ProductTitle">https://www.bol.com/nl/nl/p/m5x25-metaalschroef-nylon-din-84/9300000132859377/?bltgh=s0kF3fQf7JoEdFOJKihPAg.2_13.14.ProductTitle</a>	Verification	No
2.3.9	Nylon nut M5	1.0	18-8-2024	6	pieces	€ 0,10	€ 0,60	Dresselhaus	Hornbach	In-store availability	Verification	No
2.3.10	Nylon bolt M6	1.0	16-5-2024	12	pieces	€ 0,30	€ 3,60	Dresselhaus	Hornbach	In-store availability	Verification	No
2.3.11	Nylon nut M6	1.0	16-5-2024	12	pieces	€ 0,10	€ 1,20	Dresselhaus	Hornbach	In-store availability	Verification	No
2.3.12	Nylon bolt M8x20mm	1.0	23-7-2024	6	pieces	€ 0,55	€ 3,30	Dresselhaus	Hornbach	In-store availability	Verification	No
2.3.13	Rubber O-ring	1.0	23-7-2024	6	pieces	€ 0,06	€ 3,79	RS	RS	<a href="https://nl.rs-online.com/web/p/gaskets-o-rings/1964863?gb=s">https://nl.rs-online.com/web/p/gaskets-o-rings/1964863?gb=s</a>	Verification	No
2.3.14	Torx cap	1.0	18-8-2024	6	pieces	€ 0,06	€ 0,72	Dresselhaus	Hornbach	In-store availability	Verification	No
2.3.15	Velcro	1.0	13-5-2024	1	roll	€ 30,14	€ 30,14	VELCRO®	Bol.	<a href="https://www.bol.com/nl/nl/p/velcro-one-wrap-klittenband-16-mm-breed-25-meter-groen/9300000153121278/?bltgh=tbfy4p0C-8F07NQBY1NJgA.vgMjvkOP71cz6q4sw1xLYA_0_4.26.ProductTitle">https://www.bol.com/nl/nl/p/velcro-one-wrap-klittenband-16-mm-breed-25-meter-groen/9300000153121278/?bltgh=tbfy4p0C-8F07NQBY1NJgA.vgMjvkOP71cz6q4sw1xLYA_0_4.26.ProductTitle</a>	Verification	No
						All parts except lasercutting	€ 184,41					



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