Combination agreement

Establishing agreements for aids that are composed of products from multiple manufacturers

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Combination agreement

Manufacturer 1		Manufacturer 2
R82 A/S Parallelvej 3 DK - 8751 Gedved	and	**Scout Mobility** Tiendschuur 5 5768 SB Meijel
R82 A/S product X:Panda and customized seating		**Scout Mobility product** X10-FWD X10-RWD X10-MWD

Scope

The products are CE marked and each meet the requirements in European regulation (EU) 2017/745 with regard to Class 1 medical devices.
This agreement refers to the products listed above.
R82 seating systems (X: Panda and customized seating) mounted on electric wheelchairs from Scout.
Whereas
Customized seating from R82 A/S is delivered with a manufacturer statement according to the requirements in European regulation (EU) 2017/745 Annex XIII which states compliance and deviations to applicable standards, as well as limitation to use / use scenarios of the product.
Since the R82 A/S product is a custom-made product, the following section only applies for Scout Mobility

Scout Mobility products are CE marked and meet the requirements in European regulation (EU) 2017/745 with regard to Class 1 medical devices.
This agreement refers to the products listed above.

Obligations for the Party making the combination

The combination must not change the intended purpose of either products or modify the products in such a way that compliance with the applicable requirements may be affected.

The combiner of the products must ensure, that applicable requirements are fulfilled.

Applicable requirements examples: alignment of user weight/mass of the combined seat and base, approval for transportation in vehicles of both products (ISO16840-4 for seat and ISO7176-19 for base), material safety (biocompatibility, flammability), mechanical safety (stability, squeezing hazards, inter connection), electrical safety.

With reference to the European directive (EU) 2017/745 article 16, any Party that modify or re-label any of the products, or assist any third party to do so, including but not limited to, amending the design in such a way that compliance with the applicable requirements may be affected or changing intended use of any product, become manufacturer and undertakes the responsibility of the combination.

Manufacturers responsibility

If regulatory requirements should be changed or if design changes are made to the products, each manufacturer must consider whether this affects the validity of this agreement or not. If considered affected, the manufacturer shall notify the other manufacturer of such changes.

All customer claims must be addressed to the relevant manufacturer respectively. If one of the products causes a defect in the other product, a solution must be discussed between the manufacturers and the combiner. Each manufacturer bears responsibility for correction of its own product.

Each manufacturer is responsible for its parts in the combined product. In case of an event occur with the combination, each manufacturer will notify the national authorities if relevant.

This agreement starts on the signed date and can be ended by each of the parties by the end of each month taking in account a 3 month notice period. Termination is deemed not to prejudice the mutual compatibility of the combined products who were delivered during validity period of the combination agreement, unless this is expressly motivated in the termination.

Procedure in case of incidents

If an incident occurs with a combined product, the parties will inform each other and prioritize the importance of safety and research. They will together and in a professional manner investigate the incident adequately and without undue delay. As far as reasonably possible, parties will provide each other relevant information.
The parties agree to appoint Scout Mobility or their local distributor as primary point of contact for third parties.
This agreements do not prejudge liability aspects vis-à-vis third parties and/or between parties

R82 A/S

Date: 2023-05-15
Name: Thomas Bager
Function: Product Care Manager

Scout Mobility BV

Date: 17-04-2023
Name: Geert-Jan Linsen
Function: R&D manager

Appendix 1 Products

This covenant covers the listed wheelchair frame of Scout Mobility and the seating system of R82 A/S.

Manufacturer A R82 A/S		Manufacturer 2 Scout Mobility	Particularities
Product	*with*	*Product*	
x:panda		X10 FWD	
customized seating		X10 RWD	
		X10 MWD	

Combination is allowed to make inside intended use, based on:

Scout Mobility X10	Crash-test 89213782-03	according ISO 7176-19
R82 A/S x:panda	Crash-test 4P06462D rev1	according ISO 16840-4
Customized seating	Crash-test 4P05948A	according ISO 16840-4
	4P07589C	

The crash tests were performed with a 59 kg dummy. Maximum user weight is therefore 75 kg.

Appendix 2 Mounting

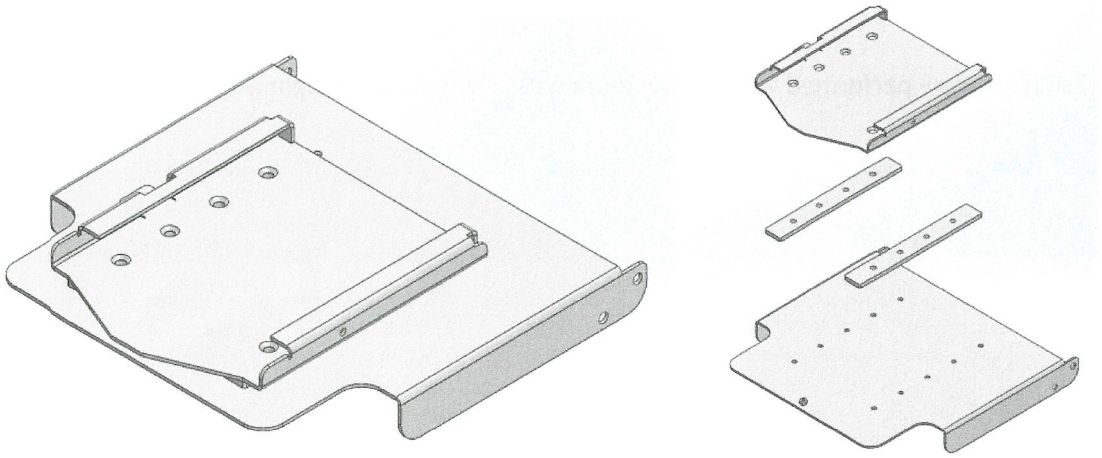
The combination of the X10 from Scout Mobility and the x:panda can be assembled by the distributor for Scout Mobility products in your country or region. Scout Mobility remains the "manufacturer" for the X10 + x:panda combination.

To achieve a safe construction, it is important that the x:panda is always installed in the same way. This way of installation will be done with a fixed adaptation package and according to a fixed installation instruction.

Assembly instruction **X10 from Scout Mobility** + R82 x:panda adapter

Mounting onto Agilo Seat Frame

Below is the assembly instruction for mounting the R82 x:panda adapter on the X10 from Scout Mobility. Footrests will be used from Scout Mobility. This interface is mounted onto the Agilo seat frame



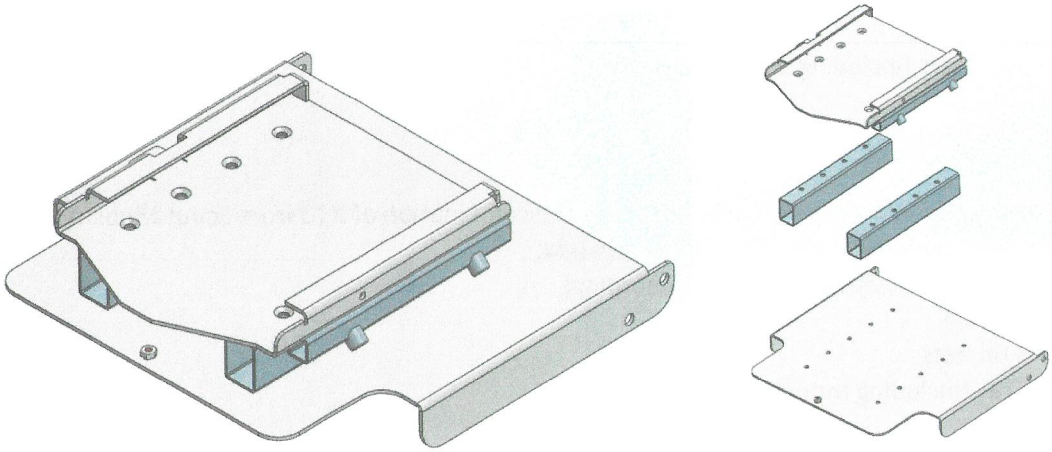
Description:

- Position the x:panda adapter relative to the base plate
  - Lay the hole patterns on top of each other
- Attach the R82 x:panda adapter to the base plate by means of 4 M6 Allen screws (ISO 10642 M6x20, countersunk head) with washers in the lock nuts

The base plate with X:panda adaptor is then assembled onto the Agilo Seat Frame with 1 M8x16 Hex bolts on each side and one M6x50 hex socket bolt at the front.

Mounting onto Agilo Seat Frame (with x:panda legrests)

Below is the assembly instruction for mounting the R82 x:panda adapter on the X10 from Scout Mobility adaptor. Footrests can/will be used from R82.



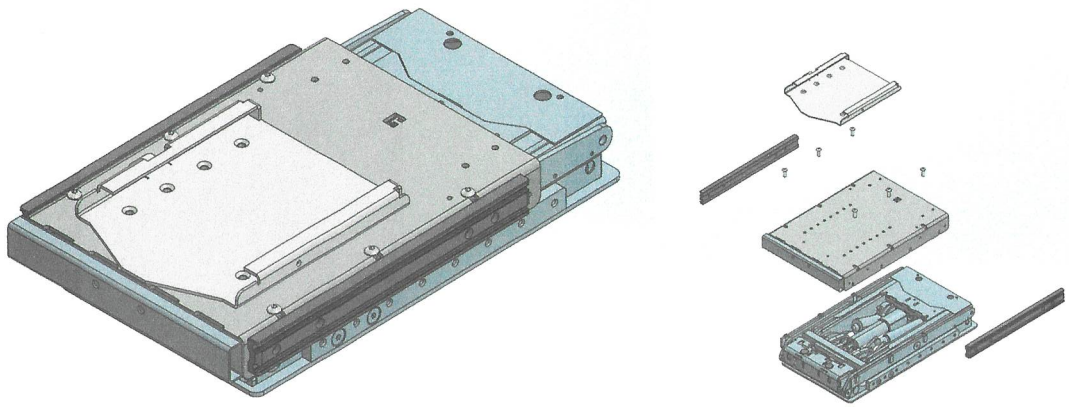
Description:

- Position the x:panda adapter incl. leg rest receivers relative to the base plate
  - Lay the hole patterns on top of each other
- Attach the R82 x:panda adapter to the base plate by means of 4 M6 Allen screws (ISO 10642 M6x55, countersunk head) with washers in the lock nuts

The base plate with X:panda adaptor is then assembled onto the Agilo Seat Frame with one M8x16 Hex bolts on each side and one M6x50 hex socket bolt at the front.

Mounting without Agilo Seat frame

Below is the assembly instruction for mounting the R82 x:panda adapter on the X10 from Scout Mobility adaptor without Agilo Seat Frame (directly onto seat lift module).



Description:

- Position the x:panda adapter relative to the base plate
  - Lay the hole patterns on top of each other
- Attach the R82 x:panda adapter to the base plate by means of 4 M6 Allen screws (ISO 10642 M6x20, countersunk head) with washers in the lock nuts

The base plate with X:panda adaptor is then assembled onto the Agilo Lift Module six M8x20 Buttonhead bolts. Arm- and legrests and accessories can be used in the side rail from Scout Mobility

Options and accessories:

If the following options/accessories are chosen for the combination of X10 from Scout Mobility + x:panda, then these will become the options/accessories of Scout Mobility BV :

- Armrests (including armrest mounting)
- Legrest
- Tray (including mounting)

If the following options/accessories are chosen for the combination of X10 from Scout Mobility + x:panda, then the options/accessories of R82 x:panda:

- Headrest (including headrest mounting)
- Legrest
- Armrests
- Tray (including mounting)

Machining operations

No machining operations have to be carried out for mounting the x:panda of R82.
If machining operations must be carried out in other parts, this needs to be requested in writing at Scout Mobility BV.

Appendix 3 Description X10 from Scout Mobility

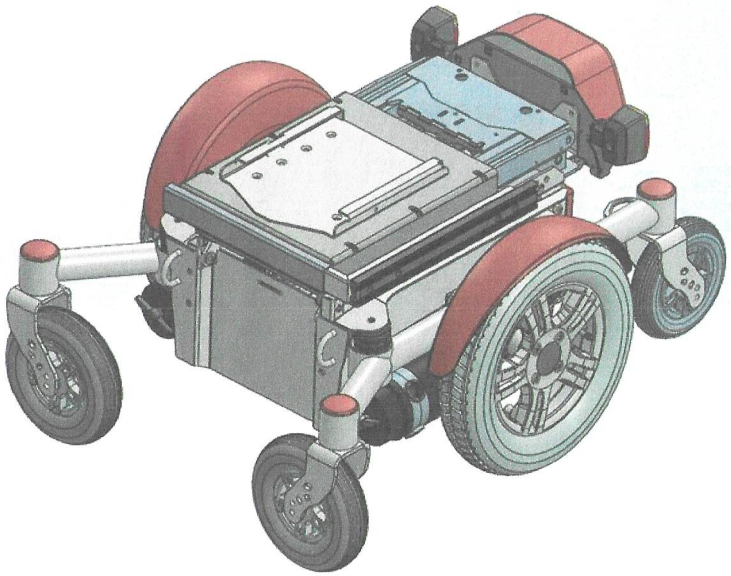
The X10 series of electric wheelchairs are characterized by simplicity and robustness, they have been developed for years of mobility pleasure.

The X10 series has different variants depending on the drive: front wheel, rear wheel or mid wheel.

The front-wheel drive X10 FWD is ideal for the user who places high demands on manoeuvrability in smaller spaces. Due to the standard application of gyroscope technology on our FWD chairs, it is also perfectly suitable for outdoor use. Naturally, all common electrical options of the Agilo seating system are available for this chair, in addition, we are here to make things that are not yet available especially for you.

Simplicity of design is the key to its reliability for our X10, because what isn't there can't lead to malfunctions. The X10 wheelchairs have the option of a minimum seat height of 39 cm including lift-tilt module.

The X10 has been tested by TüV for product safety according to the latest European standard EN12184:2014 and for safe transport according to the international crash test standard ISO7176-19:2008



Appendix 4 Description R82 x:panda

Intended use and intended environment including standard options

x:panda is a multi-adjustable seat, delivered in 4 different sizes. Each seat adjusts in 3 different widths and step less in seat depth. The back is dynamic, making it possible for the child to extend and push back against relatively light resistance and then recover into the desired sitting position. Furthermore, the back angles to make it possible to place the child with either an open or closed hip angle. When angling the seat and the base it is possible to create the desired working or resting position.

The x:panda is suitable for users needing an individual seating system e.g. children/youngsters with:
- CP at GMFCS level III-V
- Strong extensor spasticity
- Developmental delays (physical or mentally handicapped)

The many adjustment possibilities and wide range of accessories makes it possible to adjust the seat to an individual child's need for comfort and support.

If mounted on frame with labeled securement points and transport fittings the x:panda can be used for forward facing transport in motor vehicles with approved 4 point strap-type tiedown system and approved 3 point belt. For transportation the x:panda is suitable in the load range of 22 kg to specified max load for transportation.
The seating system is intended only for use with frames tested as a part of a complete wheelchair system that conforms to the performance requirements of ISO 7176-19.

Appendix 5 Combination matrix

Test Report - Combination

Responsible: Director QA

EVICE DATA								
	Name			**PRODUCT 1** x:panda size 1-4 *(Ref 2, Ref 4)*	**PRODUCT 2** X10 series		**Combination (limitation)**
Intended purpose	Manufacturer			R82 A/S	Scout Mobility B.V.		
	Mass device			6,5 to13kg	155 kg		
	Max load			80kg	160 kg		
	Max load transport			75kg			
	Lifetime			8 years	7 years		
	Description			Modular seating system Indoor /Outdoor *(Ref 7)*	*Powered wheelchair* *Class B Indoor-Outdoor*		
	DoC			MDR 2017/745 *(Ref 5)*	MDR 2017/745 (Class 1)		
Warranty				2 years 5 years on welding	2 years 5 years on welding		
Cleaning condition				☐ Wash xx degree ☒ Warewashing 60°/10 min ☐ Warewashing 85°/3 min ☒ Disinfection IPA 70% ☐ Other	☐ Wash xx degree ☐ Warewashing 60°/10 min ☐ Warewashing 85°/3 min ☐ Disinfection IPA 70% ☐ Other		
Flammability and Biocompatibility				***Description*** (e.g. test report no)			
☐ EN 17966	2016	☐ ISO 8191-1 ☐ ISO 8191-2 ☐ ISO 10993-5	N/A N/A N/A	N/A			
☒ EN 12182	2012	☒ EN 1021-1 ☒ EN 1021-2 ☒ ISO 10993-5	2014 2014 1999	*(Ref 3)*	☒ EN 1021-1 ☒ EN 1021-2 ☒ ISO 10993-5	2013 2013 2013	
☒ EN 12183	2014	☒ EN 1021-2	2006	*(Ref 3)*	N/A		
		☒ ISO 8191-2	1988	N/A			
		☒ ISO 10993-5	1999	*(Ref 3)*			
☐ EN 12184	2014				Yes		
☒ ISO 7176-16	2012	N/A	N/A	*(Ref 3)*			
Mechanical safety and stability				***Description*** (e.g. test report no)			
☐ WC-1	2009	☐ Section 1 ☐ Section 5 ☐ Section 7		N/A	N/A		

		☐ Section 8 ☐ Section 15 ☒ Section 16					
☒ FDA recognized consensus standards		☒ ISO 7176-1 ☒ ISO 7176-3 ☒ ISO 7176-5 ☒ ISO 7176-7 ☒ ISO 7176-8 ☒ ISO 7176-15 ☒ ISO 7176-16	2014 2012 2008 1998 1998 1996 2012	*(Ref 3, Ref 6)*	☒ ISO 7176-1 ☒ ISO 7176-3 ☒ ISO 7176-5 ☒ ISO 7176-7 ☒ ISO 7176-8 ☒ ISO 7176-15 ☒ ISO 7176-16	2017 2017 2017 2017 2017 2017 2017	
Transportation				***Description*** (e.g. test report no)			
☒ WC-4	2012	☐ Section 19 (Seat + frame) ☐ Section 20 Seat		N/A			
☒ ISO 7176-19	2008	(Seat + frame)		ISO 7176-19 approved w/ other frames *(Ref 3)*			
☒ ISO 7176-19	2008	R82 Adaptor		N/A	☒ ISO 7176-19	2008 – Powered wheelchair	
☒ ISO 16840-4	2009	Seat		ISO 16840-4 approved seats allows combination with ISO 7176-19 approved frames *(Ref 3)*			
Electrical Safety				***Description*** (e.g. test report no)			
☒ IEC 60601-1	N/A	☐ IEC 60601-1 ☐ IEC 60601-1-11 ☐ IEC 60601-1-2 ☐ IEC 60601-1-6	N/A N/A N/A N/A	N/A	Electrical safety ISO 7176-14:2008		
Other standards				***Description*** (e.g. test report no)			
☐ 510(k)		Product code:		N/A			
☒ Listing FDA	N/A	☒ Product code	N/A	INN Chair, adjustable, mechanical INM Chair with casters	No		
☒ISO 13485	2016	N/A	N/A	No	No		