



## **Combination Agreement**

The medical device/ devices in the table below manufactured by **Decon Wheel AB** can be combined with device/ devices in the table below manufactured by **Invacare France Operations** provided that the combination is made in an expert fashion and according to the restrictions of both manufacturers as stated in the manuals communicated by the manufacturers.

Decon Wheel AB	INVACARE FRANCE OPERATIONS
Adventus	Küschall K-series (PL 3526)
	Küschall The KSL (PL 3523)

The mutual compatibility is detailed in the table in Appendix 1. Any further details as to the products, or cases where there is no compatibility at all are also included in the table where this is the case. The enclosed appendices contain any specifications and relevant documentation for the products. The parties may add additional supporting information in appendices or in another appropriate way as necessary. The parties will jointly keep this table and any appendices or other substantiation up to date.

The device responsibility for each device listed above is held by the device's manufacturer. The devices are separately CE-marked and registered each with the responsible authority.

Mounting of the **Decon Wheel AB** medical device/s on the **Invacare France Operations** medical device/s must be executed according to the **Decon Wheel AB** mounting instruction by authorized and skilled staff only. **Decon Wheel AB** restrictions (e.g. seat width) have to be observed.

The maximum values and restrictions (e.g. user weight) mentioned in the user manuals of all devices in the combination must be observed.

Machining, bending, welding or bracing on any components is not allowed. Exceptions are allowed according to mounting instructions provided from the manufacturers.

Both parties will share the necessary documentation to demonstrate that the combination is safe to be used.

The responsibility for the verification activities including relevant documentation in respect to the combination is held by **Decon Wheel AB.** The related documentation shall be made available for **Invacare France Operations** in a timely manner upon request.

Both parties shall communicate planned changes to their device as far as the combination may be affected.

All external communication especially communication to Competent Authorities in respect to the combination shall first be communicated between the parties. In general the communication to authorities is done by the manufacturer of the device which has failed or malfunctioned.

Support for requests from authorities and requests for investigations of adverse events shall be provided by both parties within the time frame defined by the authority or manufacturer.

This combination agreement has been drawn up in two copies, one for each party. Authorized representatives have executed this agreement.

This agreements starts when duly signed by both parties for an undefined period of time and can be ended by each of the parties by the end of each month taking in account a 3 month notice period.





DECON WHEEL AB	INVACARE France Operations SAS
Södra Ekeryd 119 314 91 Hyltebruk Sweden	Route de St Roch 37230 Fondettes France
	Date: 2021 - 09 - 06

Hyltebruk, 2021-09-02

Place and date

Signature

Benny Andersson, COO

Printed name and function

Signature:

Fondettes,

Jean-Philippe BOSLE, QA/ RA Manager

Date: 2021-09-15

Signature

Witterswil,

Peter Stokman, R&D Manager



## Combination Agreement between Invacare France Operations and Decon Wheel AB

The table below shows the mutual compatibility of the products.

Invacare - manufacturer of wheelchairs	Decon Wheel AB - manufacturer of Adventus	
Küschall – K-Series, 75° frame	Artikel No. ADV4520	Appendix 2
Küschall – K-Series, 90° frame	Artikel No. ADV4570	Appendix 3
Küschall – The KSL, 75° frame	Artikel No. ADV4520	Appendix 2
Küschall – The KSL, 90° frame	Artikel No. ADV4570	Appendix 3
NOTE: The footrest to which Adventus is		
attached shall be made of aluminium square tube		

