

ET-0910 Combination agreement

Version 3



Yes, you can.

Device category	Active medical wheelchair
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The medical devices in the table below manufactured by **Vicair** can be combined with devices in the table below manufactured by **Invacare France Operations SAS** 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.

Note that all devices listed on the left side are compatible with all devices on the right side.

VICAIR	INVACARE FRANCE OPERATIONS
Vicair Active O ² seat cushion	Küschall Champion (PL 3522)
	Küschall Compact (PL 3519)
	Küschall K-series (PL 3526)
	Küschall The KSL (PL 3523)

Mounting of the **Vicair** medical device on the **Invacare France Operations** medical device must be executed in a professional manner by skilled staff only. **Vicair** and **Invacare France Operations SAS** restrictions have to be observed.

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

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

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. Both manufacturers have and will maintain a CE Technical file(s) for the device(s) listed above, to comply with the Medical Device Regulation (EU) 2017/745.

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

Invacare France Operations declares that the activity of combining devices was subject to appropriate methods of internal monitoring and verification and validation.

Invacare France Operations declares that they package the combined devices properly, including the relevant information for the users. This relevant information is also available on the websites of the device manufacturers.

Both parties shall communicate planned changes to their device and any recalls / FSN / FSCAs 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.

If an incident occurs with a combined product, the parties will inform each other first and prioritize the importance of safety and research. They will together and in a professional manner investigate the incident adequately and prosperously. As far as reasonably possible, parties will provide each other the relevant information. The parties choose to make one secretary so that third parties have one point of contact. In general, the communication to the third parties is done by the manufacturer of the device which has failed or malfunctioned.

These agreements do not prejudice liability aspects vis-à-vis third parties and / or between parties.

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Yes, you can.

Device category	Active manual wheelchair
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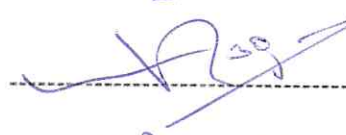
This agreement starts on 01 July 2021 for an undefined period of time and can be ended by each of the parties by the end of each month taking in account a 3 month notice period.

Termination is deemed not to prejudice the mutual compatibility of the chairs who were delivered during validity period of the combination agreement, unless this is expressly motivated in the termination.

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

VICAIR BV Bruynvisweg 5 1531 AX Wormer The Netherlands	INVACARE France Operations SAS Route de St Roch 37230 Fondettes France
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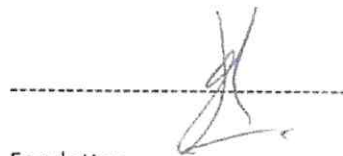
Date: 29 June 2021



Place: Wormer
Name, function:

M.P. Rogmans, CEO

Date: 25 JUN 2021



Fondettes,
Jean-Philippe BOSLE, QA/ RA Manager

Date: 25 June 2021



Fondettes,
Laurent Derche, R&D Manager