

Nibe, 01/03-2023

## **Mounting of Wolturnus Wing Back ILSA on wheelchair models of other producers**

The Wing Back ILSA is a CE-marked product, manufactured at Wolturnus A/S.

This product is in conformity with the Directive Medical products (class I) 93/42/EEC and the following standard(s)

<b>DS/EN 12183: 2014, DS/EN ISO 14971: 2012 and DS EN ISO 10993-5: 2009</b>
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Please find the EC Declaration of Conformity on page 2.

According to Article 22(a) of the Regulation (EU) 2017/745 on medical devices (MDR) the CE-marked Wing Back ILSA can be combined with any CE-marked wheelchair as long as it is mounted in line with the intended purpose and within the limits of use specified by Wolturnus.

In order to place the combined products on the market as a system, the supplier of the system (the Wolturnus partner or distributor) needs to document the combination and herewith the correct installation of the Wing Back ILSA on the CE-marked wheelchair.



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# EC DECLARATION OF CONFORMITY

with the  
**Medical products Directive**  
No. 24

We, WOLTURNUS A/S, Nibe, Denmark  
Name of manufacturer

hereby under our sole responsibility declare, that the product

Accessories for wheelchairs  
Category name

WING BACK ILSA  
Model name

manufactured at

WOLTURNUS A/S  
Factory name

HALKAERVEJ 24 B, BISLEV, 9240 NIBE, DENMARK  
Factory address

to which this declaration relates, is in conformity with the Directive Medical products (class I) 93/42/EEC and the following standard(s)

DS/EN 12183: 2014, DS/EN ISO 14971: 2012 and DS EN ISO 10993-5: 2009  
Standard(s)

**EU-declaration of conformity** in according to guidelines mentioned in Annex VII in Medical products (class I) Directive 93/42 EEC).

The technical documentation with risk analysis is available complete.

The manual for the product above is originally in Danish and in the languages in the distribution countries.

## Manufacturer

**Nibe, Denmark**  
**18. February 2020**

Date and place of issue  
(in printing)

**Peter Libak**  
**Managing Director**

Name of  
authorized person  
(in printing)

Signature of  
authorized person