

# EC Declaration of Conformity

Productname: Nitzbon Helparm, Art-Nr. 580600

Intended use: the NITZBON Helparm is to support and improve the patients arm and shoulder functionality.

Basis UDI-DI: 42601014858060062

This product is classed as a Class I product by EU Regulation 2017/745 Annex VIII - Chapter III.

Nitzbon AG  
Ergotechnik und Rehatechnik  
declares, that the following medical device:

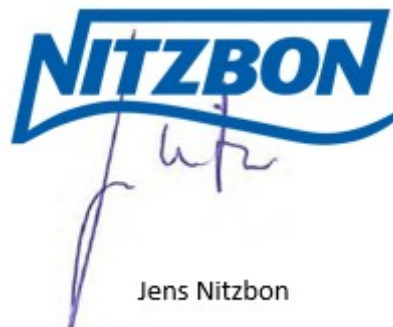
Nitzbon Helparm  
Art-Nr. 580600

is in conformity with the European Medical Device Regulation 2017/745 concerning medical devices Class 1.

SRN: DE-MF-000009971

This declaration of conformity is valid until December 31, 2023

Hamburg, 16.07.2021  
Nitzbon AG  
Ergotechnik • Rehatechnik  
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21031 Hamburg  
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fax 0049 (0)40 73922399  
email info@nitzbon.de



Jens Nitzbon



## EC Declaration of Conformity

**In accordance with Directive 93/42/EEG, Annex VII, for medical products  
and as last amended by Directive 2007/47/EG**

We, the firm Nitzbon AG  
Supplier for ergotherapy and rehabilitation equipment,  
assert sole responsibility for, and herewith certify that the designated product

Nitzbon Helparm

Art-No. 58 06 00

belongs to risk class I and is in compliance with the essential requirements of  
Directive 93/42/EEG, Annex I, as last amended by Directive 2007/47/EG.

Hamburg, 09.09.2013

\_\_\_\_\_  
(Place/Date)

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info@nitzbon.de | www.nitzbon.de

\_\_\_\_\_  
(Stamp and Signature)  
Petra Nitzbon-Grimberg

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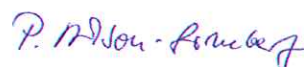
Nr. 58 06 00 / 03048

is in compliance with the essential requirements of Directive 93/42/EWG, Annex I.

Hamburg, Mai 2010

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(Ort/Datum)



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(Stempel und Unterschrift)

Petra Nitzbon-Grimberg

Nitzbon AG  
Ergotechnik • Rehattechnik

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