EU Declaration of Conformity

Manufacturer:

Nitzbon AG

SRN: DE-MF-000009971

The manufacturer declares under its sole responsibility that the medical device:

Product name:

Nitzbon Helparm, Item no. 580600

Intended purpose:

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

Basic UDI-DI: 42601014858060062

is in conformity with Regulation (EU) 2017/745 on medical devices.

The device is classified as Class I in accordance with Annex VIII, Rule 1 of Regulation (EU) 2017/745.

This declaration is valid until 31 December 2027 or until significant changes require revision of this declaration.

Hamburg, 1 January 2026
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Annex to the Declaration of Conformity

Supplement for legacy products pursuant to Regulation (EU) 2017/745 (MDR, Art. 120)

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1. Scope

This annex supplements the existing Declaration of Conformity dated January 1, 2026, for the following products that were placed on the market in accordance with Directive 93/42/EEC (MDD) and are subject to the transitional provisions of the MDR.

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2. Affected products

Product Name	UDI-DI	Basis UDI-DI	Valid until
Nitzbon Helparm	4260101483027	42601014858060062	12/31/2027

Note: The product is a Class I device and has complied with the UDI requirements of the MDR since July 2021.

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3. Legal Basis

- The products were placed on the market in accordance with MDD 93/42/EEC.
- They are subject to the transitional provisions of the MDR 2017/745 (Art. 120) and may continue to be used until the specified date.
- The UDI-DI and Basic UDI-DI comply with the requirements of the MDR (Annex VI).

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4. Declaration

The manufacturer confirms that the above-mentioned products comply with the transitional provisions of the MDR and that the UDI requirements as well as post-market surveillance, vigilance, and market surveillance for legacy devices are met.

Hamburg, April 8, 2026

Jens Nitzbon PRRC