

EU Declaration of Conformity

Manufacturer:

Nitzbon AG

SRN: DE-MF-000009971

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

Product name:

WP 4 Tension-Compression Device, Item no. 1623010

Intended purpose:

Occupational therapy, work simulation training, matching job profiles with skill profiles, and conducting occupational therapy and labour market-related performance analyses.

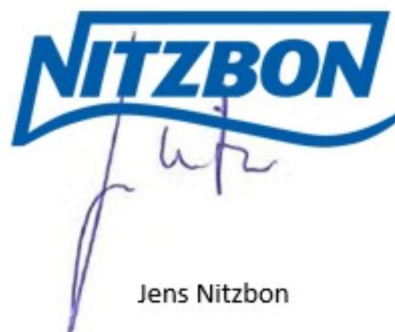
Basic UDI-DI: 4260101481623010UZ

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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The logo consists of the word "NITZBON" in a bold, blue, sans-serif font, enclosed within a blue rectangular border that has a slight wave at the bottom. Below the logo is a handwritten signature in blue ink, which appears to be "Jens Nitzbon".

Jens Nitzbon

Annex to the Declaration of Conformity

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

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.

2. Affected products

Product Name	UDI-DI	Basis UDI-DI	Valid until
WP 4 Tension-Compression Device	4260101482037	4260101481623010UZ	12/31/2027

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

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

