

DECLARATION OF CONFORMITY

We (EU MDR 2017/745 Legal Manufacturer):

QUALITEAM s.r.l.
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Single Registration Number (SRN): TO-1026079

declare under our sole responsibility for:

Product name: **Ruban Hernia Support Binder**

Product codes and UDI-DIs:

R3-S	Ruban Hernia Support 3 Band Small	8033675180342
R3-M	Ruban Hernia Support 3 Band Medium	8033675180359
R3-L	Ruban Hernia Support 3 Band Large	8033675180366
R3-XL	Ruban Hernia Support 3 Band Extra Large	8033675180373
R3-XXL	Ruban Hernia Support 3 Band Extra Extra Large	8033675180380
R3-3XL	Ruban Hernia Support 3 Band 3X-Large	8033675180397
R3-4XL	Ruban Hernia Support 3 Band 4X-Large	8033675180403
R3-5XL	Ruban Hernia Support 3 Band 5X-Large	8033675180410
R4-S	Ruban Hernia Support 4 Band Small	8033675180427
R4-M	Ruban Hernia Support 4 Band Medium	8033675180434
R4-L	Ruban Hernia Support 4 Band Large	8033675180441
R4-XL	Ruban Hernia Support 4 Band Extra Large	8033675180458
R4-XXL	Ruban Hernia Support 4 Band Extra Extra Large	8033675180465
R4-3XL	Ruban Hernia Support 4 Band 3X-Large	8033675180472
R4-4XL	Ruban Hernia Support 4 Band 4X-Large	8033675180489
R4-5XL	Ruban Hernia Support 4 Band 5X-Large	8033675180496
R5-S	Ruban Hernia Support 5 Band Small	8033675180502
R5-M	Ruban Hernia Support 5 Band Medium	8033675180519
R5-L	Ruban Hernia Support 5 Band Large	8033675180526
R5-XL	Ruban Hernia Support 5 Band Extra Large	8033675180533
R5-XXL	Ruban Hernia Support 5 Band Extra Extra Large	8033675180540
R5-3XL	Ruban Hernia Support 5 Band 3X-Large	8033675180557
R5-4XL	Ruban Hernia Support 5 Band 4X-Large	8033675180564
R5-5XL	Ruban Hernia Support 5 Band 5X-Large	8033675180571

Intended purpose:

The intended purpose of the RUBAN hernia support binder is to give compression to hernias in the abdominal area and to improve body contour distorted by hernia bulges. The expected clinical benefits are reduced pain, relieved discomfort and decreased pulling sensation from hernias.

Risk class:

Class I according to EU MDR 2017/745 Annex VIII Rule 1 (non-invasive, non-sterile).

Is in conformity with the EU MDR 2017/745 Medical Device Regulation as documented in the Technical Documentation of the product kept on file at the manufacturer address (10 years after the last commercialisation of the product)

Burolo, July 29, 2025.

Joachim Hansen
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