DECLARATION OF CONFORMITY
EU MDR 2017/745

Manufacturer (EU MDR 2017/745):

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

Qualiteam s.r.l., as the legal manufacturer, hereby declares under its sole responsibility that the medical device described below complies with the applicable requirements of Regulation (EU) 2017/745 on medical devices..

Product identification:

Product name: **QualiBelly Abdominal support**

Global Model Number (GMN) - **Basic UDI-DI: 803367519QLY2GP**

GMDN code: **10003**

Product codes and UDI-DIs:

QLY20 - S	(UDI-DI 8033675190679)
QLY20 - M	(UDI-DI 8033675190686)
QLY20 - L	(UDI-DI 8033675190693)
QLY20 - XL	(UDI-DI 8033675199412)
QLY20 - XXL	(UDI-DI 8033675199429)
QLY20 - XXXL	(UDI-DI 8033675199436)

Intended purpose:
QualiBelly Single Band provides adjustable external support to the abdominal and lumbar regions after surgery or trauma. The device helps stabilize tissues, reduce discomfort during movement and breathing, and counteract increases in intra-abdominal pressure during actions such as coughing, sneezing, or straining. It supports posture and provides localized compression during recovery. This intended purpose is the same for all size variants.

Risk class:
QualiBelly is classified as a Class I, non-sterile, non-measuring, non-invasive medical device according to MDR 2017/745, Annex VIII, Chapter III (Rule 1).

Conformity Statement
The device conforms to the General Safety and Performance Requirements (GSPRs) of Annex I of Regulation (EU) 2017/745, as demonstrated in the Technical Documentation maintained at the manufacturer's address. The Technical Documentation will be retained for at least 10 years after the last device has been placed on the market.
This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Burolo, November 15, 2025.

Joachim Hansen
CEO **QT.QLY20.DoC.EN.25.11-01**
Qualiteam s.r.l.