DECLARATION OF CONFORMITY
EU MDR 2017/745

Manufacturer (EU MDR 2017/745):

QUALITEAM s.r.l.
Via Torino 12
10010 Burolo (TO)
Italy
phone: +39 012554691
email: info@qualiteam.com
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 Advanced postoperative abdominal binder**
Global Model Number (GMN): **Basic UDI-DI: 803367519QLY0GK**
GMDN code: **10003**
Product codes and UDI-DIs:

Toddler:	**QLY TOD**	(UDI-DI 8033675190624)
	QLY2 TOD	(UDI-DI 8033675190631)
Pediatric:	**QLY PED**	(UDI-DI 8033675190617)
	QLY2 PED	(UDI-DI 8033675190648)
Adult:	**QLY - S**	(UDI-DI 8033675190204)
	QLY - M	(UDI-DI 8033675190303)
	QLY - L	(UDI-DI 8033675190402)
	QLY - XL	(UDI-DI 8033675190501)
	QLY - XXL	(UDI-DI 8033675190600)
	QLY - XXXL	(UDI-DI 8033675192994)
	QLY - 4XL	(UDI-DI 8033675190426)
	QLY40 - S	(UDI-DI 8033675192208)
	QLY40 - M	(UDI-DI 8033675192215)
	QLY40 - L	(UDI-DI 8033675192222)
	QLY40 - XL	(UDI-DI 8033675192321)
	QLY40 - XXL	(UDI-DI 8033675192420)
	QLY40 - XXXL	(UDI-DI 8033675192512)
	QLY40 - 4XL	(UDI-DI 8033675190389)

Intended purpose:
QualiBelly Advanced provides adjustable external support to the abdominal wall after surgery or trauma. The device stabilizes healing tissues, helps reduce discomfort during movement and breathing, and counteracts increases in intra-abdominal pressure during actions such as coughing, sneezing, or straining. The tri-band design allows individualized compression and access for wound inspection, and accommodates drainage tubes, stoma bags, or driver lines without cutting the device. This intended purpose is the same for all size variants.

Risk class:

QualiBelly Advanced is classified as: Class I (non-sterile, non-measuring) in accordance with EU MDR 2017/745, Annex VIII, 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.QLY.DoC.EN.25.11-01**
Qualiteam s.r.l.