

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: QualiBreath - Postoperative sternum and thorax support

Basic UDI-DI and GMDN codes shared for ALL sizes: Basic UDI-DI: 803367519QB00B9 - GMDN code 44848

Product REF and UDI-DI (EAN-13):

Adult:	QB - XS	(UDI-DI 8033675190013)
	QB - S	(UDI-DI 8033675190020)
	QB - M	(UDI-DI 8033675190037)
	QB - L	(UDI-DI 8033675190044)
	QB - XL	(UDI-DI 8033675190051)
	QB - XXL	(UDI-DI 8033675190068)
	QB - XXXL	(UDI-DI 8033675190075)
	QB - 4XL	(UDI-DI 8033675190167)
Pediatric 4–6 years:	QB 4-6	(UDI-DI 8033675190082)
Pediatric 6–8 years:	QB 6-8	(UDI-DI 8033675190099)
Pediatric 8–10 years:	QB 8-10	(UDI-DI 8033675190105)
Toddler Small:	QB-TOD1	(UDI-DI 8033675190488)
Toddler Medium:	QB-TOD2	(UDI-DI 8033675190495)
Infant Small (30 cm):	QB-INF30	(UDI-DI 8033675190914)
Infant Medium (35 cm):	QB-INF35	(UDI-DI 8033675190945)

Intended purpose:

QualiBreath provides external lateral stabilization and support to the breastbone (sternum) and chest wall after surgical procedures requiring sternotomy or opening of the thoracic cavity, or after thoracic trauma. The toddler and infant versions do not include integrated handles; this does not change the intended purpose. The integrated handles on the adult and pediatric versions allow the patient to increase encircling support during moments of increased discomfort.

Risk class:

QualiBreath 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
Qualiteam s.r.l.

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