

DECLARATION OF CONFORMITY
EU MDR 2017/745

Manufacturer (EU MDR 2017/745):

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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: QualiBra Advanced - Postoperative sternum and breast support

Basic UDI-DI and GMDN codes shared for ALL sizes:

Basic UDI-DI: 803367519QADV7

GMDN code: 10481

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

Standard cup size:

QADV - XS	(UDI-DI 8033675198989)
QADV - S	(UDI-DI 8033675198958)
QADV - M	(UDI-DI 8033675191249)
QADV - L	(UDI-DI 8033675191256)
QADV - XL	(UDI-DI 8033675190396)
QADV - XXL	(UDI-DI 8033675191737)
QADV - XXXL	(UDI-DI 8033675191744)
QADV - 4XL	(UDI-DI 8033675190129)

Plus cup size:

QADV - XS Plus	(UDI-DI 8033675191751)
QADV - S Plus	(UDI-DI 8033675198972)
QADV - M Plus	(UDI-DI 8033675191775)
QADV - L Plus	(UDI-DI 8033675191768)
QADV - XL Plus	(UDI-DI 8033675191782)
QADV - XXL Plus	(UDI-DI 8033675190433)
QADV - XXXL Plus	(UDI-DI 8033675194257)
QADV - 4XL Plus	(UDI-DI 8033675190136)

Intended purpose:

QualiBra Advanced provides external sternum stabilization and breast support after surgical procedures requiring a median sternotomy or opening of the thoracic cavity. The device helps maintain the sternal incision area dry and free from breast tissue and helps reduce mechanical stress on the sternum during breathing, coughing, and movement. The integrated pockets allow the patient to increase encircling chest-wall support during moments of increased discomfort. This intended purpose is the same for all size variants of the device.

Risk class:

QualiBra Advanced is classified as: Class I (non-sterile, non-measuring) in accordance with EU 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
Qualiteam s.r.l.

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