

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: Calla Chin and Cheek compression with neck band and cold packs

Basic UDI-DI: 803367519CLBJH

GMDN code: 61223 (Calla Chin & Cheek)

GMDN code: 42873 Cold/heat gel packs

Product REF and UDI-DIs:

CLPW-XS	(UDI-DI 8033675199351)	CPW-XS	(UDI-DI 8033675199122)
CLPW-S	(UDI-DI 8033675199368)	CPW-S	(UDI-DI 8033675199108)
CLPW-M	(UDI-DI 8033675199375)	CPW-M	(UDI-DI 8033675199092)
CLPW-L	(UDI-DI 8033675199382)	CPW-L	(UDI-DI 8033675199085)
CLPW-XL	(UDI-DI 8033675199399)	CPW-XL	(UDI-DI 8033675199115)
CLPB-XS	(UDI-DI 8033675199283)	CPB-XS	(UDI-DI 8033675199078)
CLPB-S	(UDI-DI 8033675199269)	CPB-S	(UDI-DI 8033675199054)
CLPB-M	(UDI-DI 8033675199252)	CPB-M	(UDI-DI 8033675199047)
CLPB-L	(UDI-DI 8033675199245)	CPB-L	(UDI-DI 8033675199030)
CLPB-XL	(UDI-DI 8033675199276)	CPB-XL	(UDI-DI 8033675199061)

Intended purpose:

The intended purpose is to provide support around the chin and cheek area and to hold cold packs in place for localized cooling after cosmetic or plastic surgery procedures (e.g. face lift, neck lift, chin augmentation, jaw procedures, or liposuction of chin/neck), or after other procedures or conditions where cooling and comfort in this area is desired. The device allows cold packs to be applied hands-free in a stable position, supporting user comfort and ease during recovery.

Risk class:

Calla Chin & Cheek Support is classified as: Class I (non-sterile, non-measuring) in accordance with EU MDR 2017/745, Annex VIII Rules 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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