

DECLARATION OF CONFORMITY

We (EU MDR 2017/745 Legal Manufacturer):

QUALITEAM s.r.l.

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Single Registration Number (SRN): TO-1026079

declare under our sole responsibility for:

Product name:

QualiPad seatbelt protection pad

Product codes and UDI-DIs:

QTSEPA (UDI-DI 8033675192987)

QTSEPAP (UDI-DI 8033675193885)

Intended purpose:

The intended purpose of the device is to distance the seatbelt slightly from a persons body and to provide a buffer effect to protect surgical wounds, trauma areas in chest, abdominal or hip region from a car seat belt, and to improve comfort for pregnant and obese persons, long distance and taxi drivers.

Risk class:

Class I according to EU MDR 2017/745 Annex VIII Rule 1 (non-invasive, non-sterile).

Is in conformity with the EU MDR 2017/745 Medical Device Regulation as documented in the Technical Documentation of the product kept on file at the manufacturer address (10 years after the last commercialization of the product) .

Burolo, July 29, 2025.

Joachim Hansen

CEO

Qualiteam s.r.l.