



UE DECLARATION OF CONFORMITY

According with council directive (UE) 2017/745



ALESSANDERX[®] S.p.A.

ALESSANDERX S.p.A.

Via San Leonardo da Porto Maurizio 24-26-28; postal code 59100 – Prato (PO, Italy)

Declares under its own responsibility that the products produced and sold from ALESSANDERX S.p.A. being part of the following product cluster:

ANTI-DECUBITUS PILLOW
item AMEMAB0115ITO Pillow Memory Maxi Abbraccio MX EU

Are compliant to the dispositions applicable in the following directive

REGULATION (EU) 2017/745 on MEDICAL DEVICES

And to the following international Standards

UNI CEI EN ISO 14971:2012
UNI CEI EN ISO 15223-1:2017
UNI CEI EN 1041:2013

For above purpose ALESSANDERX S.p.A. guarantees and declares under its own exclusive responsibility what below listed:

1. The devices in question are to be considered as belonging to risk class I according to Annex VIII to Regulation (EU) 2017/745 and subsequent amendments.
2. The devices in question ARE NOT MEASURING INSTRUMENTS.
3. The devices in question ARE NOT INTENDED FOR CLINICAL INVESTIGATIONS
4. The devices in question are sold in NOT-STERILE packaging
5. ALESSANDERX S.p.A. keeps and makes available to the Competent Authorities, for a period of at least 10 years from the date of manufacture of the last batch, the technical documentation proving compliance with Regulation (EU) 2017/745.

The device is registered with number: **1501002**

Code CND: Y033303

Prato, 01 June 2021

ALESSANDERX S.p.A.
CEO

DC REV.03 26.05.21_MDR

ALESSANDERX S.P.A.

Capitale Sociale 1.000.000,00 € (i.v.)

Sede Legale 59100 PRATO Via San Leonardo da Porto Maurizio, 24 - 26 - 28

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Iscritta nel Registro Imprese della Camera di Commercio di Prato

n° PO/01246380461 REA n° PO/465133



Cert. N. AJAEU/08/10598