Declaration of Conformity

ACCORDING WITH COUNCIL DIRECTIVE (UE) 2017/745

CE

ALESSANDERX® S.p.A.

Via San Leonardo da Porto Maurizio 24-26-28; postal code 59100 – Prato (PO, Italy)
Single Registration Number (SNR): IT-MF-000019975

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 MATTRESS and MEDICAL SUPPORT EQUIPMENT

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.

ALESSANDERX S.p.A.