

ALESSANDERX[®] S.p.A.

MATERASSI SOTTOVUOTO E AFFINI



Certificate of Conformity



ALESSANDERX S.p.A.

ALESSANDERX s.p.a.

via San Leonardo Da Porto Maurizio 24-26-28 - 59100-Prato, Italy

Declares that under its sole responsibility, all products manufactured and sold by ALESSANDERX SpA and its group of companies

Antistatic and Antibedsore mattress type **MRELCH0118BG0**
"Materasso Relassan Chianti h.21"

Conforms to the:
93/42/CEE and CE 2007/47 of MEDICAL DEVICE directives

And to the following international standards
UNI CEI EN ISO 14971:2009
UNI EN 980:2009
UNI EN 1041:2009

As such, ALESSANDERX SpA guarantees and declares its sole responsibility as follows:

1. Those devices satisfy the essential requirements as per attachment No. 1 of the 93/42/CEE directive as noted in the attachment VII of the above directive.
2. Those devices are NOT MEASURING INSTRUMENTS
3. Those devices are NOT UTILISED FOR MEDICAL RESEARCH
4. Those devices are sold in a NON STERILE packaging.
5. Those devices require to be treated as class 1.
6. ALESSANDERX SpA shall maintain documentation on file as required for viewing by the competent authority, for a period of at least 10 years, from the date of manufacture of the last batch, to show all technical documentation proves its conformity to 93/42/CEE directive.

The device is registered with number **509706**

Code CND: Y033306

Code GMDN: 35228

ALESSANDERX S.p.A

ALESSANDERX S.p.a.

via S. Leonardo da Porto Maurizio, 24 / 26 / 28 - 59100 Prato - Italia

tel. +39 0574 51011 fax + 39 0574 5101.235 C.F. 01246380461 p.iva IT01729090975 www.alessanderx.it info@alessanderx.it



ISO 9001 - 2000 Reg. No. 0591-A