

VERIFICATION OF CE COMPLIANCE MEDICAL DEVICE CLASS I

Applicant: Vegas Srl

Address of Applicant: Via Papa Giovanni XXIII Nr.53, 25086
Rezzato, Brescia – Italy

Product Description: Accapi FIR Bodyguard,
Mitt

Type and Model: PRO, NN435

**System progressive
attributed to
Medical Device (DM):** 36827

CND Classifications: Y0699 - Prosthesis, Orthotics, other

CE Classification: Class I

GMDN Complete Name: A body-support device
(e.g., back or joint support, shoe
insole, arch support) impregnated
with magnetized metals or
metallic compounds, that is used
to produce a weak magnetic flux field
over the body surface at the site
of application, to potentially provide
comfort or localized temporary relief
of minor aches and pains (e.g., from
muscle soreness/stiffness, arthritis).

Date of Issuance: September 16, 2008

Conclusion of Assessment:

We hereby confirm that the technical construction file and manufacturing inspection and testing processes for above-mentioned equipment comply with the essential safety requirements of EU electromagnetic compatibility 2004/108/EC directive applied codes and standards.

