

## 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,  
Undergloves

**Type and Model:** NN335

**System progressive  
attributed to  
Medical Device (DM):** 36831

**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.

