

## 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,

**Back Support** 

Type and Model: NN325

System progressive

attributed to

Medical Device (DM): 36813

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.

