



**DECLARATION
OF
CONFORMITY**

Manufacturer:

The Suremark Company
PO Box 1570
Simi Valley
CA 92062
USA

Conforming Apparatus:

X-Ray Labels

Classification:

Class I - according to Annex IX Rule 1

**Medicines and Healthcare products
Regulatory Agency Apparatus
Description:**

Surface Treatment Markers

**Medicines and Healthcare products
Regulatory Agency Registration
Reference:**

CA 009124

Technical Document Reference No:

TF0001-A

**Harmonised EMC Standard(s) and
Documents Referenced:**

EN ISO 14971:2000 Medical Devices – Application of
Risk Management to Medical Devices
Medical Devices Directive – Annex I, Essential
Requirements

EU Authorised Representative:

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We certify that the apparatus identified above conforms to the requirements of Council Directive 93/42/EEC, on the approximation of the laws of the member state relating to medical devices.

Signed:

D. R. M. Green

Date: 25th July 2006