

Schiller Médical SA

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SCHILLER
MEDICAL S.A

DECLARATION OF CONFORMITY WITH EEC DIRECTIVE 93/42

Internet : <http://www.schiller-medical.com>

E.mail : info@schiller.fr

FILE N° CEHOM00021A

PRODUCT

Name : MAGSCREEN C

Function : Positioned outside the Faraday cage within the control room, offers a remote monitoring screen with the MAGLIFE C

Classification : II b

Number : composition of number 88asXXXXX

88 : MAGSCREEN C

a : last number of the year of manufacture

s : device serial number

XXXXX : Unit number

MANUFACTURER

Manufacturer's address :

SCHILLER MEDICAL SA

4, rue Louis Pasteur

67166 WISSEMBOURG CEDEX - FRANCE

Responsible for the European Union :

SCHILLER MEDICAL SA

4, rue Louis Pasteur

67162 WISSEMBOURG CEDEX - FRANCE

Manufacturing site :

SCHILLER MEDICAL SA

4, rue Louis Pasteur

67162 WISSEMBOURG CEDEX - FRANCE

Person to be contacted

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CA



THE ART OF DIAGNOSTICS

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NOTIFIED BODY

Number 0459
Name G-MED
Address 33, avenue du Général Leclerc
92260 FONTENAY AUX ROSES - FRANCE

Person to be contacted Mr MANACH

PROOF OF CONFORMITY WITH MAIN REQUIREMENTS OF EEC DIRECTIVE 93/42 USED

Annex II GMED certificate N° 0910/B2P3/1 (in association with Standards EN ISO 9001(94) and EN 46001(96))

ENGAGEMENT

As Responsible of regulatory affairs for SCHILLER MEDICAL SA, I hereby certify that

The product defined above fills the main requirements set out in EEC directive 93/42 Appendix 1 Chapters 7 to 13.

CE labeling will be affixed in accordance with Article 17 of EEC directive 93/42.

All products are manufactured within a quality system in accordance with Appendix II - Chapters 3 of EEC directive 93/42.

All information given in the present document is valid for a period of 5 years.

Wissembourg, January 28, 2002

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Responsible of regulatory affairs



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