

Schiller Médical SA

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SCHILLER

MEDICAL S.A.

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

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DECLARATION OF CONFORMITY WITH EEC DIRECTIVE 93/42

FILE N° CESQH00017B

PRODUCT

Name : MAGLIFE C/ MAGLIFE C Plus

Function : Monitor to be used near an imaging system, on patients under MRI examination

Classification : IIb

The basic version includes ECG, SpO2, pulse, not invasive blood pressure.

The options below are available :

- %N2O, minCO2, respiration, FIO2
- %N2O, minCO2, respiration, FIO2, agents
- 2 invasive blood pressures
- recorder
- temperature

Number : composition of number 84asXXXX

84 : MAGLIFE C /MAGLIFE C Plus

a : last number of the year of manufacture

s : series number of the unit

XXXX : Unit number

MANUFACTURER

Manufacturer's address :

SCHILLER MEDICAL SA

4, rue Louis Pasteur

F-67162 WISSEMBOURG CEDEX - FRANCE

Responsible for the European Union :

SCHILLER MEDICAL SA

4, rue Louis Pasteur

F-67162 WISSEMBOURG CEDEX - France

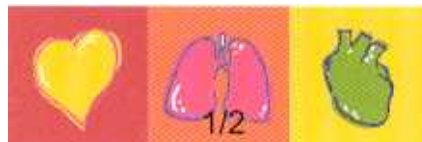
Manufacturing site :

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Ca



THE ART OF DIAGNOSTICS

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NOTIFIED BODY

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92260 FONTENAY AUX ROSES - FRANCE

Persons to be contacted : Mr MANACH

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

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 labelling 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 and 4 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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Court GOEHRY
Responsible of regulatory affairs



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