

Schiller Médical SAS

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SCHILLER

MEDICAL S.A.S

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S.A.T. : 0 820 20 22 25

DECLARATION OF CONFORMITY WITH EEC DIRECTIVE 93/42

FILE N° CEHOM0032A

PRODUCT

Name DEFIGARD 2000 EDOS
Function External transcutaneous pacemaker

Classification : II b

Number : composition of number 38asXXXX
38 : DEFIGARD 2000 EDOS
a : last number of the year of manufacture
s : device serial number
XXXX : Unit number

MANUFACTURER

Manufacturer's address :

SCHILLER MEDICAL
4, rue Louis Pasteur
67162 WISSEMBOURG CEDEX

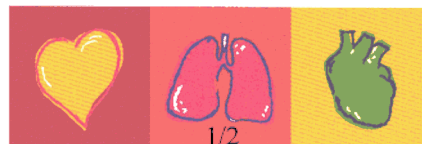
Responsible for the European Union :

SCHILLER MEDICAL
4, rue Louis Pasteur
67162 WISSEMBOURG CEDEX

Manufacturing site :

SCHILLER MEDICAL
4, rue Louis Pasteur
67162 WISSEMBOURG CEDEX

CA



THE ART OF DIAGNOSTICS

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NOTIFIED BODY

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Persons to be contacted : Mr MARTIN

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(2000) and ISO13485(1996))

ENGAGEMENT

As Responsible of Regulatory Affairs for SCHILLER MEDICAL, 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 V - Chapter 3 and 4 of EEC directive 93/42.

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

Wissembourg, July 16 2002

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Court GOEHRY
Responsible of Regulatory Affairs



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