

# NATIONAL COMPETENT AUTHORITY REPORT

***This form should be used for the exchange of medical device information between NCAR participants only. Completed forms should not be released to the public.***

1. Is this report confidential? No

## Reference and Reporter Data

2. NCA report ref. no.:	3. Local NCA reference no.:	4. Related NCA report nos.: (if any)
5. Manufacturer Ref/Recall no.:	6. Sent by: (Name and Organization)	7. Contact person: (if different from 6)
8. Tel:	9. Fax:	10. E-mail:

## Device Data

11. Generic name/kind of device :		20. CAB/Notified Body no.:
12. Nomenclature id:	13. No.:	
14. Trade Name and Model :		21a. Device approval status:
15. Software version:		
16. Serial no.:	17. Lot/batch no.:	21b. Risk Class:
18. Manufacturer:	19. Authorized rep:	
	Country: Full Address:	22. Action taken: [ ] None [ ] Safeguard action [ ] Field safety corrective action [ ] Other (specify)
Contact:	Contact:	
Tel:	Tel:	
Fax:	Fax:	
E-mail:	E-mail:	

## Event Data

23a. Background information and reason for this report:
23b. Is the investigation of the report complete ?
24a. Conclusions.:
24b. Have the manufacturer's actions been made public? [ ]Yes [ ]No
24c. The originator of this NCAR will take the lead and co-ordinate the investigation:
25a. Recommendation to receivers of this report:
25b. Device known to be in the market in (include copy of manufacturer's letter):
25c. Device also marketed as (trade name):

## Report Distribution

26a. This report is being distributed to:
[ ] The NCAR Secretariat for further distribution to FULL NCAR PARTICIPANTS.
[ ] The NCAR Secretariat for further distribution to ALL NCAR PARTICIPANTS.
[ ] EEA states, EC, and EFTA
[ ] The following targeted NCAs:
[ ] The manufacturer / authorized rep:
26b. The last NCAR distributed by this NCA was ( )

Confidentialité

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