NIPRO CORPORATION
3-9-3, Honjo-Nishi, Kita-Ku, Osaka, Japan
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EC DECLARATION OF CONFORMITY

Manufacturer :	Nipro Corporation 3-9-3, Honjo-Nishi, Kita-ku Osaka 531-8510 Japan
Authorized Representative in the European Community :	Gambro Kathetertechnik Hechingen, 72379 Hechingen, Germany
Conformity Assessment Procedure :	Annex II of the Medical Device Directive 93/42/EEC
Notified Body :	TÜV Product Service GmbH, Notified Body n° 0123
EC-Certificate :	TÜV certificate n° G1 06 01 43398 036 Issued by TÜV Product Service GmbH on Jan. 11, 2006

We, the manufacturer declare that the devices listed below meet the applicable provisions of the Medical Device Directive 93/42/EEC (MDD).
These medical devices can bear the CE mark in accordance with article 17 of the MDD

Product Group	Fistula Needle
Classification of the device :	**Class II a**
UMDNS Code	12-741
GMDNS Code	12741
Item numbers :	

F14A	F15ASR	F16B	F15AFSR
F15A	F16ASR	F17B	F15BFS
F16A	F17ASR	F14BS	F16BFS
F17A	F14 AS/AR	F15BS	F17BFS
F14AS	F16 AS/AR	F16BS	FSN 14AS
F15AS	F17 AS/AR	F17BS	FSN 15AS
F16AS	F16 AS/A	F15BSL	FSN 16AS
F17AS	F16 AM	F15BF	D-F15BSR
F15AR	F16ASM	F16BF	D-F16BSR
F16AR	F17ASM	F16AFS	D-F17BSR
F17AR	F15B	F16BFS	

This Declaration covers the devices manufactured from March 17, 2006 onwards.

Kazuo Wakatsuki
Director of International Division
Nipro Corporation
Place: Osaka, Japan
Date: April 13, 2006