

DECLARATION OF CONFORMITY

Manufacturer's name Nipro Corporation

Manufacturer's address 3-9-3 Honjo-Nishi, Kita-ku, Osaka Japan

Name of device(s) PLASTER

Type No., Model No.,
or reference No. as per attached invoice no. INV-706085

Serial No./Lot No. as per attached invoice no. INV-706085

Quantity as per attached invoice no. INV-706085

Year of manufacture as per lot no. on attached invoice no. INV-706085

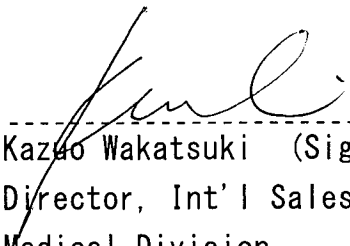
We hereby ensure and declare that the device(s) concerned meet(s) the provisions of the MDD 93/42/EEC.

This declaration is supported by:

EC quality system approval statement(Annex) No. G1 01 11 43398 014
issued by TUV Product Service GmbH(ID no.0123) on 06 November, 2001

Place Osaka, Japan

Date 02. Nov. 2007


Kazuo Wakatsuki (Signature)
Director, Int'l Sales Dept.
Medical Division
(Position)

C E R T I F I C A T E

OCT. 30, 2007

SPECIMEN : Adhesive Plastic Bandage PLASTER XL
Lot No. 071022
Sterility Lot No. 071022
Quantity 128,000

S T E R I L I Z A T I O N C O N D I T I O N S

- 1) Sterilized Date OCT. 22~23, 2007
- 2) Sterilized Gas CAPOX 30
 [Concentration : Ethylene Oxide 30%
 Carbon Dioxide 70%]
- 3) Sterilizing Temperature 50°C
- 4) Sterilizing Pressure 1.0 kg/cm²G
- 5) Sterilizing Times 3 hours
- 6) Vacuum Rates -710 mm Hg
- 7) Humidification 50%

EXAMINATION : sterility Test of Specimen.

R E S U L T

Biological Indicator Negative

J U D G E M E N T : N e g a t i v e

AUTHORIZED SIGNATURE : *M. Sugahara*
(TOYOKAGAKU Co ; LTD
Q. C. MANAGER)