EC DECLARATION OF CONFORMITY

For the following equipment：

OPERATING TABLES, GYNAECOLOGICAL EXAMINING TABLE AND DELIVERY TABLE.

(Product Name)

OT-080, OT-090, OT-110, OT-113, OT-125A, OT-128A, OT-560, OT-560A, OT-566, OT-566A, OT-600, OT-600A, OT-700, OT-700A, OT-800N, OT-800G, OT-900, OT-920, OT-950, OT-960, OT-1700, OT-1800, OT-1900, OT-2000L, OT-2000, OT-2100, OT-2200, OT-2300

(Model Designation)

Is herewith confirmed to comply with the requirements set out in Annex VII of the Council Directive 93/42/EEC:M5 concerning medical device **Class 1**. The manufacturing site for the above product complies with ISO13485:2003 + AC2007 Quality Management System Requirements for Medical Devices.

For the evaluation regarding the voltage limits, the following standards were applied：

EN 61010-1:1988+A1:1991+A2:1995, IEC 60601-1-2:2007, EN 60601-2-46, EN ISO 14971:2012, BSEN ISO 15223-1, EN 1041:2008

The following representative/importer is responsible for this declaration：

BRADI FATHI & COMPANY LTD

(Representative/Importer Name)

CHENMIN DU VANIL 6, CH-1006 LAUSANNE, SWITZERLAND

(Representative/Importer Address)

SAO Y BẢN CHÍNH
Ngày.....Tháng.....Năm 20.....

CHAIRMEN — Bradi — JAN. 19, 2017

(Position/Title) (Legal Signature) (Date)

Person responsible for making this declaration：

ST. FRANCIS MEDICAL EQUIPMENT CO., LTD.

(Manufacturer Name)

NO. 168, SEC. 2, GUNGFU RD., SAN CHUNG DIST., NEW TAIPEI CITY, TAIWAN, R.O.C.

(Manufacturer Address)

GIÁM ĐỐC
CÔNG TY TRÁCH NHIỆM HỮU HẠN THƯƠNG MẠI DỊCH VỤ KỸ THUẬT Y VŨ
Nguyễn Hoàng Vũ

MR. M. C. HONG/ DIRECTOR — JAN. 19, 2017

(Position/Title) (Legal Signature) (Date)