

Declaration of Foreign Manufacturer

To: The Department of Medical
Devices

The Ministry of Health

Sheba Medical Center

Bldg. 130

Tel-Hashomer 52621

Israel

Name of Device: **Cefaly**

Name of Manufacturer: **STX-Med s.p.r.l.**

Address of Manufacturer: **Rue des chasseurs Ardennais 4, B 4031 ANGLEUR, BELGIUM**

Telephone Number:
+3243676722

Address of Manufacturer Site: **ZI des Hauts Sarts 4eme Avenue 5-6, 4040 HERSTAL,
BELGIUM**

Name of Agent in Israel: **Methodica Business Consultancy
Ltd.**

Address of Agent: **9, Marj Ibn Amer, P.O.Box 50446, 16034 Nazareth, Israel**

Telephone Number: **+972 4 6469747**

1) We hereby certify that:

- 1.1 All the documents of the registration of the above-mentioned medical device are valid at the date of submission;
- 1.2 The medical device has not been subject to any disciplinary regulatory action (i.g., warning letter, recall) by any Competent Authority, by the date of submission for registration in Israel;
- 1.3 The medical device exported to Israel, is identical to the device as approved and marketed in one of the following countries: Australia, Canada, European Community, Japan, U.S.A.

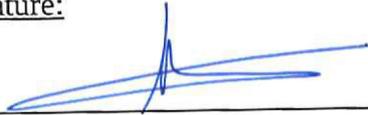
2) We hereby undertake:

- 2.1 To report to the Ministry of Health any malfunction or adverse reaction pertaining to the use of the device, which brought to our attention;
- 2.2 To report to the Ministry of Health on any change in the regulatory status of the device (e.g., change of manufacturer, change of manufacturer site).

Name of signatory:

SARTON Alain.

Signature:



Date:

14 / 12 / 2013

Title:

C.O.O.

Stamp of the manufacturer:

STX-Med Sprl Belgique
Chasseurs Ardennais B-4031 Angleur
TVA: BE 870.578.661
Tél.: +32 4 367 67 22
Fax: +32 4 367 67 02