



Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BG The Hague
THE NETHERLANDS



STATEMENT

The undersigned herewith declares that according to the Decree on Medical Devices, which is based on the European Directive 93/42/EEC concerning medical devices,

Emergo Europe B.V.
Prinsessegracht 20
2514 AP 's-Gravenhage
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

IMEDICOM Co., Ltd.
#612, #709, #804, #815, 172, LS-ro
Gunpo-Si, Gyeonggi-Do, 15807
KOREA

is authorised to manufacture and/or supply the medical device/devices mentioned below:

See product list

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to States and territories outside the European Union. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of VIETNAM .

This statement is valid until May 24, 2024.

The Hague, September 6, 2021

On behalf of State Secretary for Health, Welfare and Sport
Farmatec | CIBG

Dr. M.J. van de Velde

Mr. M.J. van de Velde
Head of Department



Ministerie van Buitenlandse Zaken

Gezien voor legalisatie van de handtekening
The undersigned legalises the signature

Our reference: 20215493
Certificate number: 33547

van/of M.J. van de Velde

De minister van Buitenlandse Zaken, voor deze,
For the minister of Foreign Affairs,

04 okt 2021 - J.J. Groen



CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia/ Country: **VIỆT NAM**
Giấy tờ, tài liệu này / *This public document*
2. do ông/bà J.J. GROEN ký
has been signed by
3. với chức danh **Viên chức BNG Hà Lan**
acting in the capacity of
4. và con dấu của: **Bộ Ngoại giao Hà Lan**
bears the seal/stamp of
được chứng nhận/hợp pháp hóa lãnh sự / *certified*
5. tại/àt: **The Hague** 6. Ngày/the: **06/10/2021**
7. Cơ quan cấp/ by: **Đại sứ quán Việt Nam tại Hà Lan**
8. Số/ No: **897B/2021**

TL. Đại sứ
Bí thư thứ Hai



Nguyễn Quỳnh Hoa
Nguyễn Quỳnh Hoa



Product List:

**Product name: B Two Vertebral Balloon Expand System
(B-Two Inflatable bone expander system syringe, B-Two Inflatable bone expander
system balloon catheter)**

Model number: T101010, T101015, T101020, T102010, T102015, T102020, T103002

**Product name: B-Two Vertebral Balloon Expand System (B-Two Vertebral Access
System)**

Model number: T103001



Ministerie van Volksgezondheid, Veiligheid en Leefomgeving
Ministry of Health, Safety and Environment

Dr. M.J. van de Velde