

Certificate of Free Sale for Exportation of Medical Devices to Vietnam

Date of Issue: 17/10/2024

Certificate Number: MT-MDF01-AA187

The **Malta Medicines Authority** has issued this Certificate of Free Sale, for the products listed in the attached **Annex I**, to:

Name of Organisation: **Advena Ltd.**

Manufacturer

Authorised Representative

Malta Business Registry Company Number: **C 76865**

Organisation Registration Number: **MT-AR-AA001**

Manufacturer Name and Address:

NRS Global Partners Sdn. Bhd.
No 30, Jalan Tasik Selatan 3,
Bandar Tasik Selatan,
57000 Kuala Lumpur,
Malaysia

Authorised Representative Name and Address:

Advena Ltd.
Tower Business Centre, 2nd Floor,
Tower Street, Swatar,
BKR 4013, Malta

This is to certify that:

- Advena Ltd. has its registered place of business in Malta.
- The product/s quoted in the attached Annex I are CE marked, in accordance with the relevant European Directives/Regulations and local legislation, as applicable hereunder:

Active Implantable Medical Device (AIMD)

EU Directive 90/385/EEC

Regulation (EU) 2017/745

S.L. 458.59

In-vitro Diagnostic (IVD)

EU Directive 98/79/EC

Regulation (EU) 2017/746

S.L. 458.59

Other medical devices

Directive 93/42/EEC

Regulation (EU) 2017/745

S.L. 458.59

- The product/s quoted in the attached Annex I may be marketed in Malta.
- The product/s quoted in the attached Annex I may be freely marketed in all the European Union member states.

Medicines Authority, Sir Temi Żammit Buildings,
Malta Life Sciences Park, San Ġwann, SGN 3000, Malta

info.medicinesauthority@gov.mt | (+356) 23 439 000

www.medicinesauthority.gov.mt

PCPS

HMA
Health of Medicines Authority



Annex I

Product Code	Device Registration Number	Description	UDI-DI
CN53CSS-SM14N00	N/A	FIESTA MAX DOTTED LATEX CONDOM	N/A
CN53PUT-SM114N00	N/A	FIESTA ULTRA THIN LATEX CONDOM	N/A
CN53PRI-SS25R00	N/A	FIESTA STRAWBERRY LATEX CONDOM	N/A
CN49PSM-SN00N00	N/A	FIESTA FORM FIT LATEX CONDOM	N/A