

Ministry of Health

Health Technology and Infrastructure Administration

Medical Devices Department



STATE OF ISRAEL

## Approval of Registration in the Book of Medical Devices and Appliances

An approval is hereby given that according to registration No: 11550401

The following Medical device / equipment:

|  |   |
|--|---|
| Name of medical device                 | SilverStream  |
| Versions                               | —   |
| Designation of device                  | Treatment and management of wounds  |
| Label                                  | SilverStream® is intended for use under the supervision of a healthcare professional for management and moisturizing of wounds such as stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, cuts abrasions and minor skin irritations. |
| Name of manufacturer and Address       | EnzySurge Ltd<br>26 Shabazi St. Rosh Ha'ayin 482126 Israel  |
| Name of manufacturing site and Address | Biological Industries Israel, Beit Haemek Ltd.<br>Kibbutz Beit Haemek 2511500, Israel   |
| Name of Supplier and Address           |   |

### Conditions

- According to the manufacturer instructions that were approved by the US FDA in approval number K093227
- Approval according to US FDA approval and Valid Quality System
- Approved for use according to the manufacturer Instructions For Use, by va physician or nurse according to a physician instructions in hospitals and clinics, or any trained and qualified person, under the supervision of a physician or a nurse

**Registered in the Book of Medical Devices and Appliances at the Ministry of Health**

**Validation of medical device marketing approval is for the designation and and labeling as described above only.**

**This approval is valid until: 24.12.2022**

**Dr. Nadav Sheffer**  
**Manager of Medical Devices and Appliances Department**  
Name of approver and position

24.12.2020  
Date of signature

