

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 (Qurion)
Versions	----
Designation of device	Treatment and management of wounds
Validated shelf life	36 months at $\leq 30^{\circ}\text{C}$
Label	SilverStream (Qurion) is intended for use under the supervision of 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 26 Shabazi St., Rosh Ha'ayin 4802126 Israel
Name of manufacturing site and Address	1. Anteco Pharma 925 Development Dr., Lodi, WI 53555 USA 2. Biological Industries Israel Beit Haemek Ltd. 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 a 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 labeling as described above only.

This approval is valid until: 28.02.2021

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

17.3.16  
Date of signature

