

Certificate of Registration

In accordance with European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

Certificate No.
ZAF/2018/03/16

Certificate issue date;
1st April 2019

Certificate expiry date;
31st March 2020

We hereby declare that

- An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.
- The EU Authorised Representative contract has been fulfilled

And the CE mark may be applied to the products listed below.

Organisation / Client:

Green Worx Cleaning Solutions PTY Ltd
Unit 1 New Port Business
Quartz Road, Kya Sands Business Park
Kya Sands
Johannesburg
South Africa

Products:

Odorite™ All-in-One Enzymatic Surgical Instrument Cleaner

Competent Authority Information:

Class I Medical Device Directive registration is with the Malta Competition and Consumer Affairs Authority (MCCAA) and the below registration has been issued.

DVC-MT-18-04-000007

Authorised Representative Labelling Information:

EC **REP** Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

Advena Limited.

Registered office;

Tower Business Centre, 2nd Flr, Tower Street,
Swatar, BKR 4013. Malta
Registered in Malta No. C 76865

☎ +44 1926 800153

Email; info@advenamedical.com

Authorised Signature:



This certificate is subject to the organisation maintaining their documentation in compliance with the regulations stated in this certificate.

This certificate is for the exclusive use of Advena Ltd's client and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Unit 1
 New Port Business
 Quartz Road
 Kya Sands Business Park
 Kya Sands
 Tel # +27 11 708 6626
 Fax # +27 11 708 6625
 E Mail info@greenworx.co.za
 Website www.greenworx.co.za
 Co. Reg. # 2012/213244/07



Declaration of Conformity


I hereby declare that the products described in this document meet the Council Directive provisions that apply to them as per the European Communities Council Directive 93/42/EEC, as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states:

Product Name	Odorite™ All-in-One Enzymatic Surgical Instrument Cleaner
General Product Description	Enzymatic Detergent / Cleaner
Legal Manufacturer & Address	GreenWorx CS Unit 1, New Port Business, Quartz Road, Kya Sands Business Park, Kya Sands, Johannesburg, South Africa.
Variants	1, 5 and 25 Litre Containers (Liquid form only)
Intended Use	Enzymatic surgical instrument cleaner used prior to disinfection.
MD Directive Classification	Class I
GDMN Code	38773
GMDN Descriptor	Medical Device Decontamination Agent
Notified Body	Not Applicable
EU Authorised Representative	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013, Malta.
Medical Device Directive Assessment Route	Self-certification as per Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

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Standard / Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1: 2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

Approval			
I hereby confirm that GreenWorx accepts full responsibility for the establishment and maintenance of the Declaration of Conformity and will amend this document should any of the information change, which will also be communicated to our EU Authorised Representative immediately.			
Name & Surname	John Coetzee	Position	Chief Executive Officer
Signature		Date	21 March 2018

Revision History			
Rev. No.	Compiled by	Date	Description
01	John Coetzee	2018-03-21	First issue