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;
3rd May 2018

Certificate expiry date;
31st March 2019

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:

Enzymatic Detergent / 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.

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
Website
Co. Reg. # 2012/213244/07

GreenWorx
BIO CLEANING SOLUTIONS

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, 2nd 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.

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@green-worxs.co.za
Website www.green-worxs.co.za
Co. Reg. # 2012/213244/07

GreenWorx
BIO CLEANING SOLUTIONS

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