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.

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.**
- **Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.**

Therefore, these devices have met the requirements of the council directive and the CE mark may be applied to the products listed below.

Certificate No: CE/ZAF/2018/03/16	Issue Date: 01st April 2020	Expiry Date: * 31st March 2021

Please note, due to the implementation date of the new medical device regulation (EU 2017/745) this certificate is subject to a review of the client's technical documentation before the 26th May 2020, whereupon a new Certificate of Registration is issued once compliance to the medical device regulation has been achieved.

Legal Manufacturer	EU Authorised Representative (EC REP)
Green Worx CS Unit 1 New Port Business, Quartz Road, Kya Sands Business Park Kya Sands, Johannesburg, South Africa	Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names	MCCAA Device Registration Reference(s)
Odorite™ All-in-One Enzymatic Surgical Instrument Cleaner	DVC-MT-18-04-000007

Competent Authority
Malta Competition and Consumer Affairs Authority (MCCAA) Mizzi House, National Road, Blata I-Bajda, HMR 9010 Malta. Tel: +356 2395 2000 Email: info@mccaa.org.mt

This certificate is issued by:	Authorised Signature:
Advena Limited **Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013.** **Malta. Tel: +44 1926 800153 Email: info@advenamedical.com** **Registered in Malta No. C 76865**	**Anthony Kirby – Managing Director (Malta)**

This certificate is subject to the organisation maintaining their documentation in compliance with the directive 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.

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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