

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 01455****Issued To:**

**Antec International Limited
Windham Road
Chilton Industrial Estate
Sudbury
Suffolk
CO10 2XD
United Kingdom**

In respect of:

The design and manufacture of chemical disinfectants for use with invasive and non-invasive Medical Devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1996-10-30**

Date: **2021-03-29**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

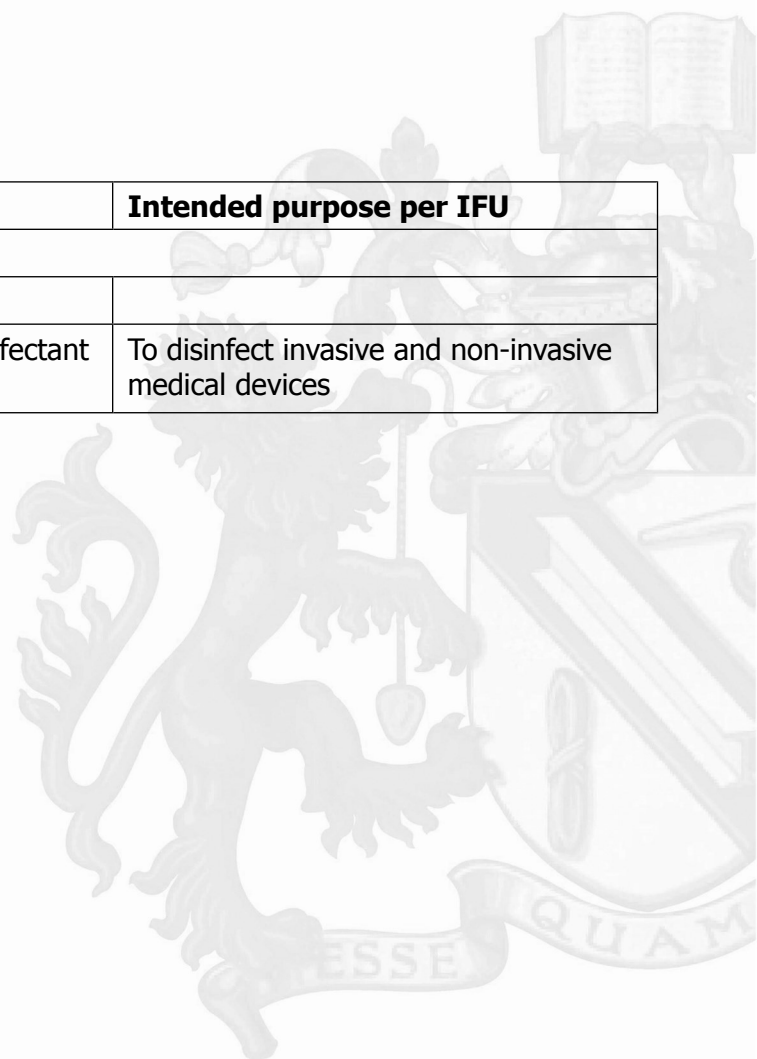
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Supplementary Information to CE 01455

Issued To:

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Windham Road
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Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN Code		
47631	Percarbonate powder – chemical disinfectant	To disinfect invasive and non-invasive medical devices

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:**Service(s) supplied**

A E Adams
Unit 4
Mackley Industrial Estate
Small Dole
West Sussex
BN5 9XR
United Kingdom

Packaging

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Representative

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Certificate History

Certificate No: **CE 01455**
Date: **2021-03-29**
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Date	Reference Number	Action
30 October 1996		First Issue.
17 April 2003		Re-issued in new format.
29 June 2006	4737476	Certificate renewal.
21 March 2010	7447689	Upgrade from Annex V to Annex II.
23 June 2011	7686555	Certificate renewal.
24 June 2016	8549271	Certificate renewal. Addition of A E Adams as significant subcontractor.
15 February 2019	7780090	Traceable to NB 0086.
14 January 2020	3086175	Addition of EU Representative Emergo Europe. Addition of supplementary device table.
Current	3390577	Certificate renewal. Clarification of product name.

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