

### **Declaration of Conformity** and CE mark Certification

Sterilisation Packaging Products manufactured by Westfield Medical Limited are classified as CE mark, Class 1, Non-Sterile Devices in accordance with the 93/42/EEC - 2007/47/EC Medical Device Directive. All products are manufactured in an approved ISO9001:2015 and ISO13485:2016 quality management system environment.

The products are registered with the UK, Medicines and Healthcare Products Regulator Agency, (Devices Division) (MHRA) with Reference No CA000213, as non-sterile 'Sterilisation Packaging for devices intended for terminal sterilisation'.

> Sterilisation Pouches & Reels Flat & Gusseted Plasma Sterilisation Pouches and Reels Sterilisation Bags Plain Closure & Heat Seal Supawrap, Medicrepe, Crepe & Plain wrapping paper Synthetic Reinforced Non-Woven Supadrape, Supaspun SMMS outer tray wraps

Westfield Medical declares that the products meet the requirements of Annex 1 of the Medical Device Directive by conforming to the requirements of ISO11607-1&2:2019 and EN868-2-10 (2017-2018) as appropriate.

In accordance with the views of EUCOMED & SBA, which Westfield fully supports, the CE mark will only appear on the outer label and not each individual item.

Jim Baldwin Technical & Development Director

GN-D004

Issue 3

22<sup>nd</sup> February 2019

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msales@westmed.co.uk





## Kitemark<sup>™</sup> Licence

This is to certify that:

**Westfield Medical Limited** 

Second Avenue Westfield Trading Estate Midsomer Norton Radstock BA3 4DP United Kingdom

Holds Kitemark Licence Number:

KM 07788

In respect of:

BS EN 868-5 - Packaging for terminally sterilized medical devices sealable pouches and reels of porous and plastic film construction.

This issues the right and Licence to use the Kitemark in accordance with the Kitemark Terms and Conditions governing the use of the Kitemark, as may be updated from time to time by BSI Assurance UK Ltd (the "Conditions"). All defined terms in this Licence shall have the same meaning as in the Conditions.

The use of the Kitemark is authorized in respect of the Product(s) detailed on this Licence provided at or from the above address.

For and on behalf of BSI:

Gary Fenton, Global Assurance Director

First Issued: 1/02/1988

Latest Issue: 10/09/2014



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...making excellence a habit."

### No. KM 07788

BS EN 868-5:2009 - Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction.

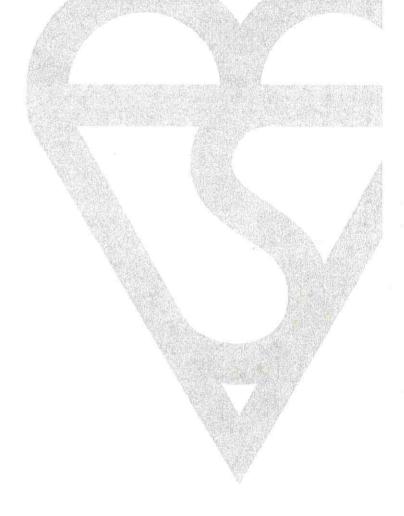
This Kitemark licence covers packaging for terminally sterilized medical devices in the size ranges detailed below:

**Width** Minimum = 50 millimetres

Maximum = 900 millimetres

**Length** Minimum = 100 millimetres

Maximum = 600 metres



First Issued: 1/02/1988

Latest Issue: 10/09/2014





# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Westfield Medical Limited

Second Avenue

Westfield Trading Estate

Midsomer Norton

Radstock BA3 4DP

United Kingdom

Holds Certificate Number:

MD 591173

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and supply of paper bags, wrapping papers, heat sealable and self-seal pouches, tray liners, tube materials and reel converted from paper, film combinations, paper/film laminates, coated papers and spunbonded olefins for packaging of medical devices for sterilisation, the supply of medical sterilisation accessories. The design, development and manufacture of pouches to maintain used instruments in a moist state to aid post-operative cleaning. Previous certificate expired on 13/01/2019 Recertification audit ended 01/11/2018

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-01-14

Latest Revision Date: 2019-02-25

bsi.



Effective Date: 2019-01-23 Expiry Date: 2022-01-13

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory