Digitally signed by Latîşev Anastasia
Date: 2020.04.16 00:11:33 EEST
Reason: MoldSign Signature
Location: Moldova

Westfield Medical
Sterilisation Barrier Solutions

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

Westfield Medical Limited
Second Avenue, Westfield Trading Estate,
Midsomer Norton, Radstock BA3 4DP
Registered in England No. 2768124
+44 (0) 1761 408800 sales@westmed.co.uk
+44 (0) 1761 413714 www.westmed.co.uk
FM01170 MD591171

Kitemark™ 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

...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

bsi.

By Royal Charter

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

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

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