 <small>A MEMBER OF THE STERIMED GROUP</small>	<b>Declaration of Conformity (DoC) and CE Marking</b>	Doc No: GN-D004-MEG-AUG24 Effective Date: 02/02/2023
	Document Owner: T&D Director	Revision No: 008

This Declaration is issued under the sole responsibility of Westfield Medical Ltd (SRN GB-MF-000019794) and applies to the products detailed below.


Sterilisation Packaging Products manufactured by Westfield Medical Limited are determined to be risk Class I/Rule I in accordance with the rules of Annex VIII and are CE marked as Non-Sterile Devices in accordance with the MDR 2017/745 and UK MDR 2002. All products are manufactured in an approved ISO9001 and ISO13485 Quality Management System environment.

The products are registered with the UK Medicines and Healthcare Products Regulator Agency, (Devices Division) (MHRA) as non-sterile 'Sterilisation Packaging for devices intended for terminal sterilisation'.

The following bespoke sterilisation products are classified as *13735 Sterilization packaging, single-use* under the Global Medical Device Nomenclature system.

The Basic UDI-DI for these products are listed in the table below by product;

WML Part No.	Description	Basic UDI-DI
MEG300520	Pouch, Flat, Printed, Megro, 50x200mm	503695321PA
MEG300525	Pouch, Flat, Printed, Megro, 50x250mm	503695321PA
MEG300715	Pouch, Flat, Printed, Megro, 75x150mm	503695321PA
MEG300727	Pouch, Flat, Printed, Megro Logo Design, 75x270	503695321PA
MEG301020	Pouch, Flat, Printed, Megro Logo Design, 100x200	503695321PA
MEG301030	Pouch, Flat, Printed, Megro Logo Design, 100x300	503695321PA
MEG301527	Pouch, Flat, Printed, Megro Logo Design, 150x270	503695321PA
MEG302027	Pouch, Flat, Megro design. 200x270mm	503695321PA
MEG302235	Pouch, Flat, Printed, Megro, 225x350mm	503695321PA
MEG302540	Pouch, Flat, Printed, Megro Logo Design, 250x400	503695321PA
MEG311030	Pouch, Gusseted, Printed, Megro Logo Design, 100x50x300mm	503695326PL
MEG311540	Pouch, Gusseted, Printed, Megro Logo Design, 150x50x400mm	503695326PL
MEG312038	Pouch, Gusseted, Printed, Megro Logo Design, 200x50x400mm	503695326PL
MEG320050	Reel, Flat, Printed, Megro Logo Design, 50mm x 200m	503695331PD
MEG320075	Reel, Flat, Printed, Megro Logo Design, 75mm x 200m	503695331PD
MEG320100	Reel, Flat, Printed, Megro Logo Design, 100mm x 200m	503695331PD
MEG320150	Reel, Flat, Printed, Megro Logo Design, 150mm x 200m	503695331PD

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MEG320200	Reel, Flat, Printed, Megro Logo Design, 200mm x 200m	503695331PD
MEG320250	Reel, Flat, Printed, Megro Logo Design, 250mm x 200m	503695331PD
MEG320300	Reel, Flat, Printed, Megro Logo Design, 300mm x 200m	503695331PD
MEG320400	Reel, Flat, Printed, Megro Logo Design, 400mm x 200m	503695331PD
MEG330075	Reel, Gusseted, Printed, Megro Logo Design , 75mm x 38mm x 100m	503695336PP
MEG330100	Reel, Gusseted, Printed, Megro Logo Design , 100mm x 50mm x 100m	503695336PP
MEG330150	Reel, Gusseted, Printed, Megro Logo Design , 150mm x 50mm x 100m	503695336PP
MEG330200	Reel, Gusseted, Printed, Megro Logo Design , 200mm x 50mm x 100m	503695336PP
MEG330250	Reel, Gusseted, Printed, Megro Logo Design , 250mm x 65mm x 100m	503695336PP
MEG330300	Reel, Gusseted, Printed, Megro Logo Design , 300mm x 65mm x 100m	503695336PP
MEG330400	Reel, Gusseted , Printed, Megro Logo Design , 400mm x 65 mm x 100m	503695336PP
WPSS060100	Pouch, Self Seal, 60x100mm	503695323PE
WPSS090140	Pouch, Self Seal, 90x140mm	503695323PE

Westfield Medical declares that the devices listed on this DoC fulfil the requirements of and are in conformity with the MDR (2017/745) and UK MDR 2002 by conforming to the requirements of ISO11607-1:2020+A1:2023, ISO11607-2:2020+A1:2023, and EN868-2 to 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. The same approach is also taken in respect of the UKCA mark.

Westfield Medical Ltd has appointed Sterimed SAS, as our Authorised Representative and their offices are situated at;

Route de Céret, 66110 Amélie-les-Bains, France.

Website: [sterimed.fr](http://sterimed.fr), email: [regulatory.affairs@sterimed.fr](mailto:regulatory.affairs@sterimed.fr), Tel: +33468879700

Jim Baldwin



 <p>A MEMBER OF THE  STERIMED GROUP</p>	<b>Declaration of Conformity (DoC) and CE Marking</b>	Doc No: GN-D004-MEG-AUG24 Effective Date: 02/02/2023 Revision No: 008
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Technical & Development Director and Person Responsible for Regulatory Compliance at Westfield Medical Ltd, Second Avenue, Westfield Trading Estate, Radstock. BA3 4DP.