



EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the Medical Devices Directive 93/42/EEC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex II clause 4 of the Directive) undertake an EC Design Examination on the
stated products to ensure their conformity with the requirements of the Directive which apply to them.
The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER: Tissuemed Ltd
5 Killingbeck Drive
Leeds
West Yorkshire
LS14 6UF
United Kingdom

PRODUCT NAME: TissuePatch Product Family

PRODUCT DESCRIPTION: Absorbable Surgical Sealant and Barrier

OTHER DETAILS: TissuePatch
TissuePatchDural
TissuePatchDS
TissuePatchSF

DESIGN DOSSIER REFERENCE: Tissuepatch3 Design history File (13.1)

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No: 0088/0944645/00257

Original Approval: 30 August 2006

Current Certificate: 29 August 2016

Certificate Expiry: 30 August 2021

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



EC DESIGN EXAMINATION CERTIFICATE CERTIFICATE 0088/0945645/00257 SUPPLEMENT

**Tissuemed Ltd
5 Killingbeck Drive, Leeds,
West Yorkshire, LS14 6UF
United Kingdom**

LRQA hereby confirms that the change(s) detailed below have been reviewed in conjunction with the approved Design Dossier and the EC Design Examination remains valid.

This supplement is only valid in association with the EC Design Examination certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	29 August 2016	Renewal on job no 142406.
1	27 October 2016	Addition of TissuePatch DS-P

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