



## EC Certificate - Full Quality Assurance System

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

**No.** CE 621938  
**Issued To:** **Medprin Biotech GmbH**  
**Gutleutstraße 163-167**  
**60327 Frankfurt am Main**  
**Germany**

In respect of:

**Design, development and manufacture of absorbable dural repair patches: Regenerative Dural Repair Patch (ReDura™).**

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 0086):

Frank Lee, EMEA Compliance & Risk Director



2019-03-19  
RODIA TIKRA  
Vadybininkas  
Andrius Markūnas

First Issued: **12 February 2016**

Date: **26 July 2016**

Expiry Date: **24 March 2021**

...making excellence a habit™

Page 1 of 1

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.

bsi.



By Royal Charter

**EC SERTIFIKATAS – Pilnos kokybės užtikrinimo sistema**  
**Medicinos prietaisų direktyva 93/42/EEC, II Priedas išskyrus 4 skyrių**

Nr. **CE 621938**  
Išduotas: **Medprin Biotech GmbH**  
**Gutleutstrase 163-167**  
**60327 Frankfurtas prie Meino**  
**Vokietija**

Atsižvelgiant į:

**Dizainas, absorbuojamo kietojo smegenų dangalo kūrimas ir gamyba: Regeneracinis kietojo smegenų dangalo lopas (ReDura™).**

Remiantis mūsų kokybės užtikrinimo sistemos eksperimentavimu laikantis Tarybos Direktyvos 93/42/EEC, II Priedo išskyrus 4 skyrių reikalavimų. Kokybės užtikrinimo sistema atitinka direktyvos reikalavimus. Norint tiekti rikai III klasės produktus, reikalingas II Priedo 4 skyriaus sertifikatas.

BSI vardu ir vardu, Notifikuotas Organas aukščiau minimai Direktyvai (Notifikuoto Organo Nr. 0086):

(parašas)

Frank Lee, EMEA atitikimo ir rizikos direktorius

Pirmo išdavimo data: **2016 vasario 12**    Data: **2016 liepos 26**    Galioja iki: **2021 kovo 24**



2019-03-19  
Vartotojas tikros  
Vadybininkas  
Andrius Markūnas