



## Declaration of Conformity

**Manufacturer** Guangdong Biolight Meditech Co., Ltd.  
**Address** No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai, P.R. China  
**European Representative** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg Germany  
**Product** Syringe Pump used for intravenous injection administration  
**GMDN Code** 13217  
**Model Code** P500 (SN:P-085-E-000001~ P-085-E-999999)

**Classification:** Class II b , rule 11 of Annex IX of the MDD 93/42/EEC

**Conformity Assessment Route:** Annex II without chapter 4 of the MDD 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. We are exclusively responsible for this DoC. All supporting documentations are retained under the premises of the manufacturer

### DIRECTIVES

**General applicable directives:**

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

**Standard:**

All applicable harmonized Standard (published in the Official Journal of the European Communities).

**Notified Body:** TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

**Identification number:** 0123

**(EC) Certificate(s):** G1 17 10 49957 033

**Expire date of the Certificate:** 2020-03-19

**Start of CE marking:** 2016-02-17

**Place, Date of Issue:** Zhuhai, China, 2018-04-20

Signature

Jin Liang

Name Jin Liang

Position Chief Engineer