



EC Declaration of Conformity to Medical Devices Directive 93/42/EEC

Manufacturer: Foshan Biours Biosciences Co., Ltd.

Manufacturer's Address: 302, 3F, Tower B, Complex Building, No.13 East Xile Road, Leping Town,  
Sanshui District, Foshan City 528137, Guangdong Province, CHINA

Device/s: Polymer Hydrogel Patch

Description: Cooling Gel Sheet

Brand name: Frescopad

EC Product Class: Class 1

Date: May 14, 2019

## Declaration of Conformity

Foshan Biours Biosciences Co., Ltd., declares that device/s Polymer Hydrogel Patch listed on the attached Device Schedule conform/s to the relevant provisions of the EC Council Directive 93/42/EEC dated 20 October 2005 and is in accordance with the Annex VII, as implemented by the European Union's Medical Devices Regulations.

Foshan Biours Biosciences Co., Ltd., confirms that no other application has been lodged with another Notified Body for the same device related Quality Management System.

Foshan Biours Biosciences Co., Ltd., agrees to develop, implement and maintain a formally-recognised Quality Management System to ensure continued adequacy and efficacy.

Foshan Biours Biosciences Co., Ltd., agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Foshan Biours Biosciences Co., Ltd., confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Foshan Biours Biosciences Co., Ltd., agrees to inform the appointed Notified Body [Ente Certificazione Macchine Srl.] of any planned or unplanned substantial change to the Quality Management System.

Foshan Biours Biosciences Co., Ltd., agrees to inform the appointed Notified Body [Ente Certificazione Macchine Srl.] of any planned or unplanned significant change to the Device Schedule, including significant design change to devices.

This declaration of conformity is valid from March 27, 2019.

Ente Certificazione Macchine Srl.

Authorised Signatory:

Mr. Paul Huang

General Manager

