

CE Documentation Review



No. OP190327.FBBUD30

Holder:	Foshan Biours Biosciences Co., Ltd. Room 302, 3F, Room 201, 202, 203, 2F, Tower B, F1 Complex Building, No.13 East Xile Road, Leping Town, Sanshui District, Foshan City, Guangdong Province, China
Review goal:	Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII
Product:	Polymer Hydrogel Patch
Model(s):	BI-1-01 ~ BI-1-08, BI-2-01 ~ BI-2-05, BI-3-01 ~ BI-3-08, BI-4-01 ~ BI-4-08, BI-5-01 ~ BI-5-08, BI-6-01 ~ BI-6-08, BI-7-01 ~ BI-7-08, BI-8-01 ~ BI-8-08.
Classification:	Class I (accordingly to the Manufacturer's declaration)
Review output:	We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. TMGD19031317231. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

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Expiry date 26 March 2024

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