

Certificate Number
152 CE

Initial Certification Date
23 July 1997

Certificate Issue Date
23 July 2012

Certificate Expiry Date
22 July 2017

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

*AMTAC Certification Services Limited
Davy Avenue
Knowhill
Milton Keynes
MK5 8NL UK
☎ Telephone
+44 (0)1908 857 750
Email: acsl@intertek.com*

EC Certificate

PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC for Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

Organization:

BDF LIMITED

Grangestone, Girvan, Ayrshire, KA26 9PD, Scotland
And at
Doonview, Patna, Ayrshire, KA6 7JW, Scotland

See attached schedule

Authorized Signatory:



AMTAC Certification Services Limited, Milton Keynes, UK