

DECLARATION OF CONFORMITY


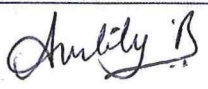
Certificate No. 20

Issue Number: 05 (CC2014-06-02)

Name of Manufacturer:	SmithKline Beecham Limited
Address of Manufacturer:	SmithKline Beecham Ltd, EUCH CQ, 11 Stoke Poges Lane, Slough, Berks, SL1 3NW, UK
Name of Device:	Biopsy Punch & Curette
Intended Use:	The devices are sterile, invasive devices for transient use to be used in the area of minor surgical procedures. They are intended for single use only.
Device Classification:	Class IIa
Product Lines and Formula Number:	Biopsy Punch: 2.0 (62377), 3.0 (62376), 3.5 (61463), 4.0 (62375), 5.0 (62366), 6.0 (62374), 8.0mm (62373) Curette: 4.0 (70592), 7.0mm (61569)
Batch number:	All lots released from <i>June 2014</i>
Address of Fabrication Site(s):	Formula Supplied from Fabrication Site:
sfm medical devices GmbH Bruckenstrasse 5, 63607 Wachtersbach, Germany	Biopsy Punch & Curette
SaFeMed spol.s.r.o. Trabantska 292, 19015 Praha 9/Satalice, CZECH REPUBLIC	Curette - moulding of the protection cap for the currettes, overmoulding the blade and packaging only.

We, the undersigned, hereby declare that the medical device specified above conforms to the Essential Requirements listed in Annex I of Council Directive 93/42/EEC (as amended by directive 2007/47/EC).

This declaration is supported by EC Quality Certificate (Annex V) No GB06/70120 .00 issued by SGS, Notified Body No. 0120 and Quality System Approval Certificate applied by SmithKline Beecham Limited, EUCH CQ to products specified on Certificate No GB06/70119.

Place	EUCH CQ, Slough, UK	Stiefel Regulatory, Stockley Park, UK
Date	04 JUL 2014	4 th JUL 2014
Signature		
Full Name	Laura Sinden	Ambily Banerjee
Position	Compliance Manager, EUCH CQ GlaxoSmithKline Consumer Healthcare	Director, Regulatory Affairs, Europe Stiefel, a GSK company

(GSK staff to confirm any proposed registrations with SmithKline Beecham Ltd EUCH CQ)