Technical File

	 	
	Product group	Dermatological Instrument
	Directive 93/42/EII Product group Short name of product name Product name Sterilization method	Biopsy punches
1	93 C Product name	Biopsy punch
	Sterilization method	EOG sterilization
	Classification	Class II a (Rule 6)
2	Declaration of conformity	See attached Declaration of conformity "Biopsy Punches" issued on 2008-10-15
3	General description of the product	See attached Declaration of conformity "Biopsy Punches" issued on 2008-10-15
4	Essential requirements	Recorded in the design history file.
-	checklist	
5	Applied standards	See attached Declaration of conformity "Biopsy Punches" issued on 2008-10-15
6	Intended use	Used for cutting, dissecting and/or filing of tissue mostly skin of human's body This product is single use.
7	Function	This product has a handle, and a blade. This product is Used for cutting, dissecting and/or filing of tissue
<u> </u>		mostly skin of human's body.
8	Accessories and detachable parts	N/A
9	Material	Standards and components of materials each parts - Manufacturing control standard of the biopsy punch [KH-M-BP140]
10	Mechanical drawings	Drawing ledger Handle: MTH01 issued on 1990-02-07 Blades: SM-TB002-K-01 issued on 2001-10-10
11	Label and instructions for use	Recorded in the design history file.
12	Packaging	Product specification sheet
13	Manufacturing process	Manufacturing flow chart - Manufacturing control standard of the biopsy punch [KH-M-BP-010]
14	Inspection and quality assurance techniques	Manufacturing control standard of the biopsy punch [KH-M-BP]
15	Shelf life	5 years after sterilization
16	Sterilization validation	Procedure for EOG sterilization validation of biopsy punches [KQKH0A] Report for EOG sterilization validation of biopsy punches [20040906]
17	EOG residuals	≦250ppm
18	Mechanical tests	Recorded in the design history file.
19	Risk evaluation	Application of risk management to medical device [KQFI11A] Risk analysis sheet KADI11A-F2 <rev.2> No. 5</rev.2>
20	Clinical evaluation	Recorded in the design history file.
21	Biocompatibility	Recorded in the design history file.
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Technical File

	CI:	Product group	Dermatological Instrument
1	Classifi Directive	Short name of product	Biopsy punches
	icat 93/	Product name	Dermal curette
	ication 93/42/EI	Sterilization m e t h o d	EOG sterilization
	of EC	Classification	Class II a (Rule 6)
2	Declaration of conformity		See attached Declaration of conformity "Biopsy Punches" issued on 2008-10-15
3	General description of the product		See attached Declaration of conformity "Biopsy Punches" issued on 2008-10-15
4	Essential requirements		Recorded in the design history file.
5	Applied standards		See attached Declaration of conformity "Biopsy Punches" issued on 2008-10-15
6	Intended use		Used for curettage of tissue mostly skin This product is single use.
7	Function		This product has a handle, and a blade. This product is Used for curettage of tissue mostly skin.
8		ssories and chable parts	N/A
9	Material		Standards and components of materials each parts - Manufacturing control standard of the dermal curette [KH-M-DC131]
10	Mechanical drawings		Drawing ledger Handle: SM-CH008-K-03 issued on 2004-02-27 Blades: SM-CU003-K-03 issued on 2005-12-15 Products: SM-CQ001-K-01 issued on 2003-03-17
11	Label and instructions for use		Recorded in the design history file.
12	Рас	kaging	Product specification sheet
13	Manufa	acturing process	Manufacturing flow chart - Manufacturing control standard of the biopsy punch [KH-M-DC012]
14		tion and quality nce techniques	Manufacturing control standard of the biopsy punch [KH-M-DC]
15	S h e	lf life	5 years after sterilization
16	Sterilization validation		Procedure for EOG sterilization validation of dermal curettes [KQKH06A] Report for EOG sterilization validation of dermal curettes [070106]
17	EOG residuals ≦250ppm		≦250ppm
18	Mech	anical tests	Recorded in the design history file.
19	Risk	evaluation	Application of risk management to medical device [KQFI11A] Risk analysis sheet KADI11A-F2 <rev.2> No. 6</rev.2>
20	Clinic	al evaluation	Recorded in the design history file.
21	Bioco	mpatibility	Recorded in the design history file.

Document Number: KCKH07-F-01(Rev.1)



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Technical File

İ	Product grou	,
	Directive Product group Short name of product	Lioney punches
1	93 Product nam	
	metho	
	Classificatio	(1.130 1.4 (1.14) 6)
2	Declaration o	
3	General description of the produc	See attached Declaration of conformity "Bionsy Punches" issued
4	Essential requirement	S Decorded in the decimal to the
5	Applied standard	on 2008-10-15
6	Intended us	Used for curettage of tissue mostly skin This product is single use.
7	Function	This product has a handle, and a blade. This product is Used for curettage of tissue mostly skin.
8	Accessories and detachable parts) NIA
9	Materia	Standards and components of materials each parts - Manufacturing control standard of the biopsy blades [KH-M-BB010]
10	Mechanical drawings	Drawing ledger Handle: SM-CH009-K-01 issued on 2006-05-25 Blade: SR-TB005-1-01 issued on 1998-03-30
11	Label and instructions for use	Described in the state of the s
12	Packaging	Product specification sheet
13	Manufacturing process	Manufacturing flow chart - Manufacturing control standard of the biopsy blade [KH-M-BB020]
14	Inspection and quality assurance techniques	
15	Shelf life	
16	Sterilization validation	Procedure for EOG sterilization validation of biopsy blades [KQKH54A] Report for EOG sterilization validation of biopsy blades [080930]
17	EOG residuals	
18	Mechanical tests	Recorded in the design history file.
19	Risk evaluation	Application of risk management to medical device [KQFI11A] Risk analysis sheet KADI11A-F2 <rev.2> No. 8</rev.2>
20	Clinical evaluation	Recorded in the design history file.
21	Biocompatibility	Recorded in the design history file.



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