Technical File

1	Classification of Directive 93/42/EEC	Product group	Dermatological Instrument
		Short name of product	Biopsy punches
		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 checklist		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 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 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
20	Clinical evaluation		Recorded in the design history file.
21	Biocompatibility		Recorded in the design history file.

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Technical File

1	Classification of Directive 93/42/EEC	Product group	Dermatological Instrument
		Short name of product	Biopsy punches
		Product name	Dermal curette
		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 checklist		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	Accessories and detachable 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	Packaging		Product specification sheet
13	Manufacturing process		Manufacturing flow chart - Manufacturing control standard of the biopsy punch [KH-M-DC012]
14	Inspection and quality assurance techniques		Manufacturing control standard of the biopsy punch [KH-M-DC]
15	Shelf 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
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. 6
20	Clinical evaluation		Recorded in the design history file.
21	Biocompatibility		Recorded in the design history file.

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Technical File

1	Classification of Directive 93/42/EEC	Product group	Dermatological Instrument
		Short name of product	Biopsy punches
		Product name	Biopsiblade
		Sterilization method	EOG sterilization
		Classification	Class Ⅱa (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 checklist		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	Accessories and detachable parts		N/A
9	Material		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		Recorded in the design history file.
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		Manufacturing control standard of the biopsy blade [KH-M-BB]
15	Shelf life		5 years after sterilization
16	Sterilization validation		Procedure for EOG sterilization validation of biopsy blades [KQKH54A] Report for EOG sterilization validation of biopsy blades [080930]
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. 8
20	Clinical evaluation		Recorded in the design history file.
21	Biocompatibility		Recorded in the design history file.

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