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	Gamma sterilization
		Classification	Class Ⅱa (Rule 6, Subclause 1,No Indent)
2	Declaration of conformity		See attached Declaration of conformity "Biopsy Punches" issued on 2016-08-31
3	General description of the product		A) Stainless steel tube blade with polypropylene plastic handle. Each in blister pack and 20 pcs. in a dispenser box, 50 boxes per export carton. B) Stainless steel tube blade with polypropylene plastic handle with plunger. Each in blister pack and 20 pcs. in a dispenser box, 50 boxes per export carton. Dimension of knife : —See attached Declaration of conformity "Biopsy Punches" issued on 2016-08-31
4	Essential requirements checklist		Recorded in the design history file. MDD Annex I – KCFI02A-F-7,Rev.13,control number 25-02, Rev.7 issued on 2016-08-31
5	Applied standards		See attached Declaration of conformity "Biopsy Punches" issued on 2016-08-31
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		Blades: SM-TB002-K-02 issued on 2016-04-22 Handle: SM-TH013-K-01 issued on 2015-06-25 SM-TH001-K-01 issued on 2001-10-10 951018-01 issued on 1995-10-18 SM-TH002-K-01 issued on 2001-10-10 SM-TH004-K-13 issued on 2015-06-24 Plunger:SM-TP005-K-08 issued on 2006-04-27 SM-TP004-K-05 issued on 2006-04-27 Spring:SM-TP002-K-02 issued on 2005-02-21 Products: SM-TQ001-K-01 issued on 2003-03-17 SM-TQ002-K-02 issued on 2015-06-25
11	Label and instructions for use		Examination of label [M15602+QQ2T]、[M16202+QQ2T] Biopsy punch primary package 1406B、1602B、1602C Biopsy punch secondary package 1406B、1602B
12	Packaging		Seal peal test [M15331=KQ2T] Sterility test [M13Z26=PQ2T] Drop test [M13Y11=FQ2T] Microbial barrier test [M15827=KQ4T] Transportation test [M15609=PF2T]

13	Manufacturing process	Process management regulations [KQFI05A] Processing conditions table [NO.80C]、[NO.80D] 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 gamma sterilization validation of ISO 11137-2 Method VDmax^{25} [KQKH65A] Report for gamma sterilization validation of biopsy punches [20150804] Report for gamma sterilization validation of biopsy punche with plunger [20160823]
17	EOG residuals	N/A
18	Mechanical tests	Resistance test [M15825=KQ3T]、[M16822=KQ2A] Sharpness test [M16224=KQ3T] Visual and functional test [M16224=FQ2T]、[M16822=FQ2A]
19	Risk evaluation	Summary of Risk evaluation for Biopsy punch [KQFI11A-F4 No.05 issued on 2016-08-31]
20	Clinical evaluation	Summary of Clinical evaluation for Biopsy punch [KQKH23A-F2 No.05 issued on 2016-08-31]
21	Biocompatibility	Summary of Biocompatibility for Biopsy punch [KQKH64A-F2 No.05 issued on 2016-08-31]
22	Usability	Summary of Usability engineering for Biopsy punch [KQKH61A-F4 No.05 issued on 2016-08-31]

Approval	Create
16.8.31	16.8.31

Revision History— 1 ／ 1

Revision No.	Prepared on	Matter for Revision	Reason for Revision	Create by
1	2015/09/03	N/A	Create New	Shinoda
2	2016/03/04	Section : 2,3,4,5,11,12,16,18, 19,22	Revision of sections	Shinoda
3	2016/08/31	Section : 2,3,4,5,10,16,18,19, 20,21,22	Revision of sections	Shinoda