Technical File

1	Classification of Directive 93/42/EEC	Product Group	Dermatological Instruments
		General Product Group	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 2020-10-21
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 2020-10-21
4	Essential requirements checklist		Recorded in the design history file. MDD Annex I – KH-M-MD-05-0022007
5	Applied standards		See attached Declaration of conformity "Biopsy Punches" issued on 2020-10-21
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 SM-TB001-K-03 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-14 issued on 2015-06-29 SM-TH007-K-03 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-03 issued on 2015-10-21 SM-TQ005-K-02 issued on 2015-06-25
11	Label and instructions for use		Examination of label [M15602+QQ2T]、[M200211+QQ8H]

12	Packaging	<Primary package> Size:32.8 or 35 × 140mm <Secondary package> Size:85 × 140 × 75mm, Quantity:20 pcs. <Tertiary package> Size:448 × 300 × 402mm, Quantity:20 × 50 pcs.
13	Manufacturing process	Process management regulations [KQFI05A] Processing conditions table [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 Punch [20190820] Report for gamma sterilization validation of Biopsy Punch with plunger [20200512]
17	EOG residuals	N/A
18	Mechanical tests	Resistance test [M19826=FK0S]、[M19827=LF0Y] Sharpness test [M19823=SK3S] Visual test [M19821=FQ6T] Functional test [M19826=FQ5T] Seal peal test [M19827=FK3S-1]、[M19827＝FK3S-2] Sterility test [M19821=PF9S]、[M19822=PF10S]、[M13Z26=PQ2T] Microbial barrier test [M19821=PF9S]、[M19822=PF10S]、[M17429=PS3X] Transportation test [M19821=PF9S]、[M19822=PF10S]
19	Risk evaluation	Summary of Risk evaluation for Biopsy Punch [RM-05-0022007-F4]
20	Clinical evaluation	Summary of Clinical evaluation for Biopsy Punch [KH-M-CE-05-0022006]
21	Biocompatibility	Summary of Biocompatibility for Biopsy Punch [KH-M-BE-05-0022006]
22	Usability	Summary of Usability engineering for Biopsy Punch [KH-M-UE-05-0022007]

Approval	Create
開発 '20.10.21 五十君	'20.10.21

Revision History— 1 ／ 1

Revision No.	Prepared on	Matter for Revision	Reason for Revision	Created 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
4	2017/08/28	Section : 1,2,3,4,5,10,12,16,18, 19,20,21,22	Revision of sections	Shinoda
5	2018/08/31	Section : 1,2,3,4,5,11,12,16,18, 19,20,21,22 Revision of the format (Rev.4 → Rev.5) Document number (KH-M-TF-03-R-02→KH-M-TF-05-R)	Change document number Revision of sections	Shinoda
6	2019/01/16	Section : 2,3,5	Revision of sections	Shinoda
7	2019/09/04	Section : 4,10,11,16,18,19,20, 21,22	Revision of sections	Shinoda
8	2020/07/30	Section : 2,3,4,5,11,16,18,19,20, 21,22	Revision of sections	Shinoda
9	2020/10/21	Section : 2,3,5	Revision of sections EC certificate registration No. update	Shinoda