


Technical File

1	Classification of Directive 9 3 / 4 2 / E E C C	P r o d u c t G r o u p	Dermatological Instruments
		G e n e r a l P r o d u c t G r o u p	Biopsy Punches
		P r o d u c t N a m e	Biopsy Punch
		S t e r i l i z a t i o n M e t h o d	Gamma sterilization
		C l a s s i f i c a t i o n	Class II a (Rule 6, Subclause 1, No Indent)
2	Declaration of conformity	See attached Declaration of conformity "Biopsy Punches KH-M-DC-III Rev.29" issued on 2021-08-06	
3	General description of the product	<p>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.</p> <p>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.</p> <p>Dimension of knife: – See attached Declaration of conformity "Biopsy Punches KH-M-DC-III Rev.29" issued on 2021-08-06</p>	
4	Essential requirements checklist	Recorded in the design history file. MDD Annex I – KH-M-MD-05-0022107	
5	Applied standards	See attached Declaration of conformity "Biopsy Punches KH-M-DC-III Rev.29" issued on 2021-08-06	
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	<p>Blades: SM-TB002-K-02 issued on 2016-04-22 SM-TB001-K-03 issued on 2016-04-22</p> <p>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</p> <p>Plunger: SM-TP005-K-08 issued on 2006-04-27 SM-TP004-K-05 issued on 2006-04-27</p> <p>Spring: SM-TP002-K-02 issued on 2005-02-21</p> <p>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</p>	
11	Label and instructions for use	Examination of label [M15602+QQ2T], [M20211+QQ8H]	

12	P a c k a g i n g	<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 [KQF105A] 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	S h e l f l i f e	5 years after sterilization
16	Sterilization validation	Procedure for gamma sterilization validation of ISO 11137-2 Method V _{Dmax} ²⁵ [KQKH65A] Report for gamma sterilization validation of Biopsy Punch [20210720] Report for gamma sterilization validation of Biopsy Punch with plunger [20210803]
17	E O G r e s i d u a l s	N/A
18	Mechanical tests	Resistance test [M19826=FK0S], [M19827=LF0Y] Sharpness test [M19823=SK3S] Visual test [M19821=FQ6T] Functional test [M19826=FQ5T] Seal peel test [M19827=FK3S-1], [M19827=FK3S-2] Sterility test [M19821=PF9S], [M19822=PF10S] 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-05-0022107-F4]
20	Clinical evaluation	Summary of Clinical evaluation for Biopsy Punch [KH-M-CE-05-0022105]
21	Biocompatibility	Summary of Biocompatibility for Biopsy Punch [KH-M-BE-05-0022106]
22	U s a b i l i t y	Summary of Usability engineering for Biopsy Punch [KH-M-UE-05-0022107]
23	P S U R	Summary of PSUR issued on 2021-05-25

Signature: 

Approved by: Makoto Mori, Senior Corporate Officer

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
10	2021/08/06	Section : 2,3,4,5,11,16,18,19,20,21,22,23 Revision of the format (Rev.5 → Rev.6)	Revision of sections	Shinoda