Technical Documents

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Category	**Pathological instruments**
Product group	**Microtome blades**
Product name	**FEATHER MICROTOME BLADE**
GMDN codes	**Microtome blade, Single use 42440**
Contents of technical documentation	
Product Description	**- General description of the devices** **- Intended purpose of use** **- Manufacturing process** **- Classification**
Technical requirements	**- Identification of technical requirement** **- Annex I Essential requirement check list** **- Standards applied**
Design	**- Risk analysis** **- Labeling / IFU** **- Product life** **- Drawings**
Change records	
Declaration of conformity	**F_Dec._IVD_08**

Approved by; **Quality Control Dept.** **Quality Manager; KATSUHIKO KOMORI** **Signature**	**Author;** **Quality Control Dept.** **DAISUKE SUEMATSU** **Signature**

Product Description

General description of the devices

< FEATHER MICROTOME BLADE >

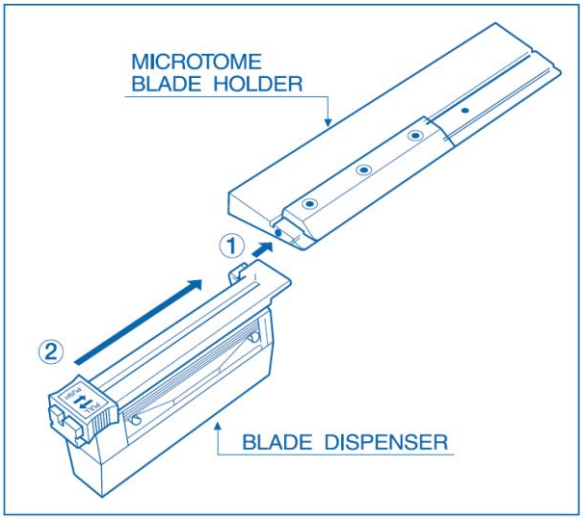
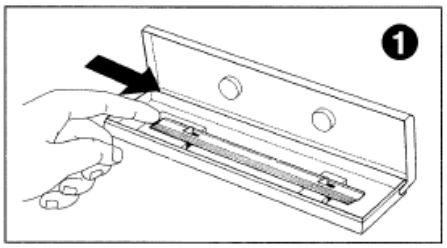
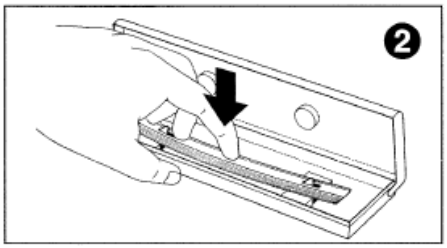
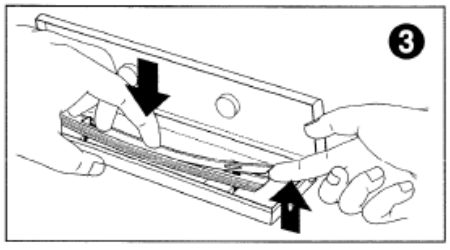


Infomation	Material	Dimension (T)x(W)x(L)	Edge Finish
S-35 "Fine" For thin sectioning of paraffin embedded tissue blocks. It has earned a high reputation for superior cutting performance and durability.	Stainless Steel	0.254 x 8 x 80 Edge Angle 35°	Resin Coating Platinum Spattering
R-35 "Routine" For thin sectioning of paraffin embedded tissue blocks. Especially suited for routine microtomy operations. Double spattering increases edge strength and durability even when sectioning right after trimming with the same blade position.	Stainless Steel	0.254 x 8 x 80 Edge Angle 35°	Resin Coating Platinum Spattering
A-22 For extra thin sectioning of paraffin embedded tissue blocks. Especially suited for fibered tissues / biopsy.	Stainless Steel	0.254 x 8 x 80 Edge Angle 22°	Resin Coating Platinum Spattering
A-35 "Superior" For thin sectioning of paraffin embedded tissue blocks. Especially suited for hard tissue block sectioning and ribbon sectioning. Durable and stable life after trimming.	Stainless Steel	0.254 x 8 x 80 Edge Angle 35°	Resin Coating Platinum Spattering
N-35 "Long Duration" For thin sectioning of paraffin embedded tissue blocks. Long blade life, no need to move the blade in real sectioning after trimming.	Stainless Steel	0.254 x 8 x 80 Edge Angle 35°	Resin Coating Platinum Spattering
New **N-35HR** For thin sectioning of paraffin embedded tissue blocks. Especially recommended for hard tissue and routine sectioning.	Stainless Steel	0.254 x 8 x 80 Edge Angle 35°	Resin Coating Platinum Spattering
S-22 "Super Fine" For extra thin sectioning of paraffin embedded tissue blocks. Especially recommended for laboratory use. Under some circumstances, blade life may be limited because of the ultra-thin edge.	Stainless Steel	0.254 x 8 x 80 Edge Angle 22°	Resin Coating Platinum Spattering
HIGH-PROFILE For thin sectioning of paraffin embedded tissue blocks. Especially suited for ribbon sectioning with rotary microtome.	Stainless Steel	0.31 x 14 x 75.7 Edge Angle 35°	Resin Coating Platinum Spattering
C-35 For thin cryo-sectioning. Specially ground for cryostat use to eliminate curling or wrinkling problems.	Carbon Steel	0.245 x 8 x 80 Edge Angle 35°	
S-35L For thin sectioning of large tissue blocks. Same quality as the S-35. (120mm)	Stainless Steel	0.254 x 8 x 120 Edge Angle 35°	Resin Coating Platinum Spattering
S-35LL For thin sectioning of large tissue blocks. Same quality as the S-35. (180mm)	Stainless Steel	0.254 x 8 x 180 Edge Angle 35°	Resin Coating Platinum Spattering



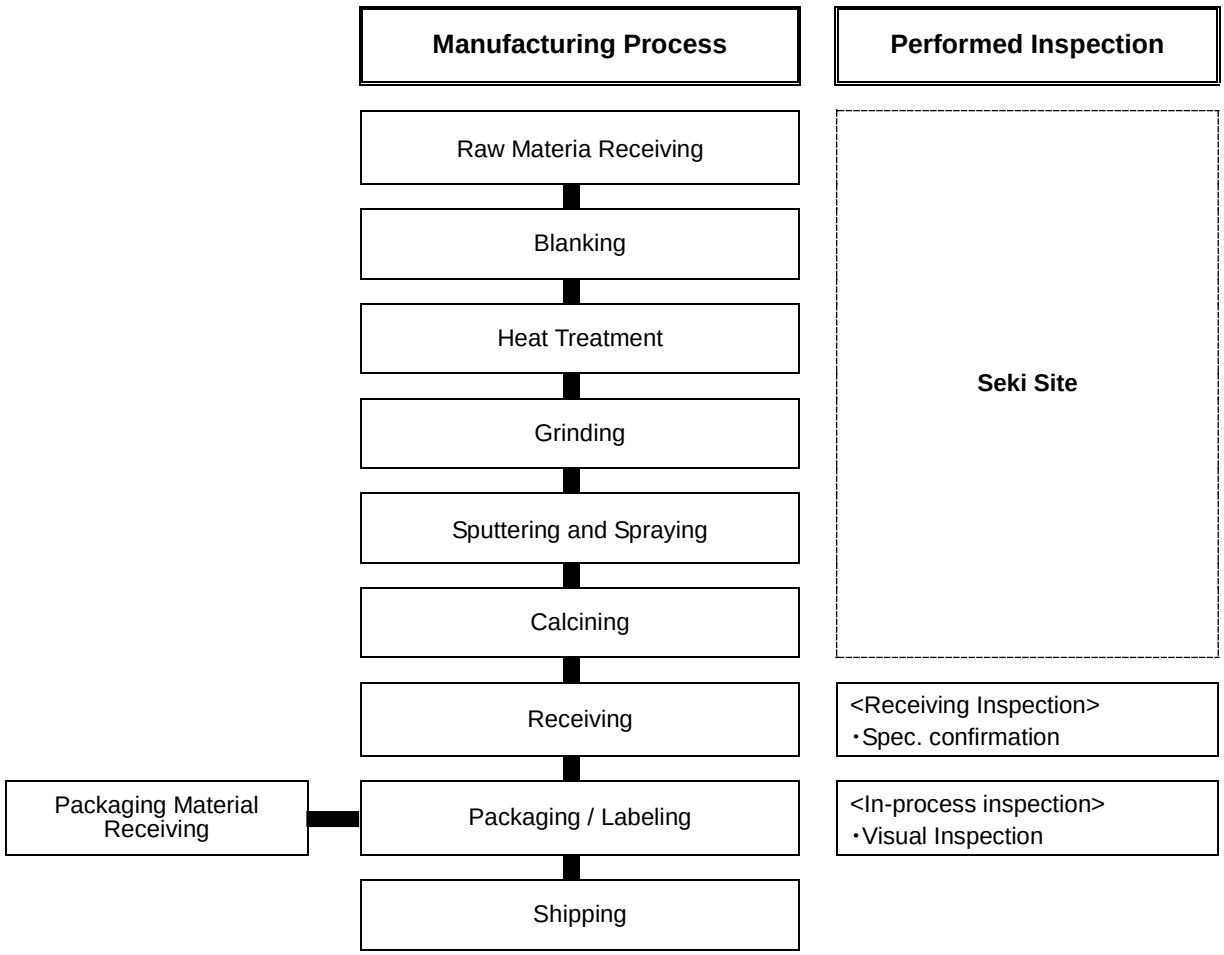
SH35W（超硬タイプ）

Components	Raw materials
BLADE	**Stainless Steel** **Carbon Steel (C35)** **High Speed Tool Steel (H-35S)** **Tungsten carbide (SH35W)**
Dispenser	**ABS resin**
Sales unit package	**Paper box**

Intended use	**MICROTOME BLADE intended for sectioning paraffin-embedded tissue or frozen tissue for making pathologic specimen.**
Operation	**S35, R35, A22, A35, N35, H35HR, S22, HIGH PROFILE, C35, SH35W**  **S35L, S35LL**   

Manufacturing process

MICROTOME BLADE



Classification	**Other** **This device is not listed on a *Annex II*.**

Technical requirements	
Identification of technical requirement	**In-vitro Diagnostic Medical Device Directive 98/79/EC** **Annex I Essential requirement**
Annex I checklist	**FEATHER MICROTOME BLADE** *See attachment*
Standards applied	**ISO 13485:2003, ISO 14971:2007, EN 980:2003, EN 1041:2008**

Design	
Risk analysis	**Risk management report** **FEATHER MICROTOME BLADE** *See attachment*
Labelling / IFU	**- Dispenser: ABS resin** **- Sales unit package: Paper box** *See attachment*
Product life	**NA**

Drawings:

Type/Models		Holders
S35	**Drawing No.9680101**	**FEATHER MICROTOME BLADE HOLDER; No.130A, No.160, No.240S, No.240D, No.130AE, No.160E, No.240E**
R35	**Drawing No.9680601**	
A22	**Drawing No.8100001**	
A35	**Drawing No.9681101**	
N35	**Drawing No.9680801**	
N35H	**Drawing No.9680901**	
S22	**Drawing No.9680001**	
N35HR	**Drawing No.8120000**	
High-Profile	**Drawing No.9680701**	**No.150C-H**
C35	**Drawing No.9680301**	**No.130C-A, No.130C-S, No.130C-AO, No.160C**
SH35W	**Drawing No.8190001**	**No.150SH**
S35L	**Drawing No.9680401**	**No.240E, No.240D**
S35LL	**Drawing No.9680501**	
H35S	**Drawing No.9746001**	**No.158HD, No.180HD**

Legal Manufacturer **FEATHER SAFETY RAZOR CO., LTD.** **Sales** **FEATHER SAFETY RAZOR CO., LTD.** **OVERSEAS TRADE DIVISION**	**Address** **3-3-70, Ohyodo-Minami, Kita-ku, Osaka 531-0075, Japan**
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Design facility **FEATHER SAFETY RAZOR CO., LTD.** **RESEARCH & DEVELOPMENT CENTER**	**Address** **1-17, Hinode-Machi, Seki-City, Gifu, 501-3873 JAPAN**
EC-representatives **pfm medical ag**	**Address** **Wankelstraße 60, 50996 Cologne, Germany**

Change records

Date	Contents/details	Documentations	Contact to Notified body
2010/8/10	Update & Revise of the document number TDF_IVD_08		
2012/01/20	Specification in components of the devices.		
2013/04/01	Overseas trade division address change		Change notification
2015/08/17	R & D division address change		
2015/12/26	Performed inspection has been added to manufacturing process.		