Technical Documents

File No. TDF_IVD_04_Rev.05
Issued date; December 26, 2015

Category	**Pathological instruments**
Product group	**Trimming blades**
Product name	**FEATHER TRIMMING BLADE** **FEATHER SAFETY TRIMMING KNIFE BLADE**
GMDN codes	**Autopsy knife 37826**
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_06, F_Dec._IVD_10**

Approved by; **Quality Control Dept.** **Quality Manager; YUJI KIMURA** **Signature**	**Author;** **Quality Control Dept.** **KENJI USAMI** **Signature**

Product Description	
General description of the devices	**< FEATHER TRIMMING BLADE >** **No.130**  **No.130R**  **No.260** 

Components	Raw materials
BLADE	Carbon Steel
Individual package	Rust preventive paper
Sales unit package	Paper box

< FEATHER SAFETY TRIMMING KNIFE BLADE >

No.M130RC



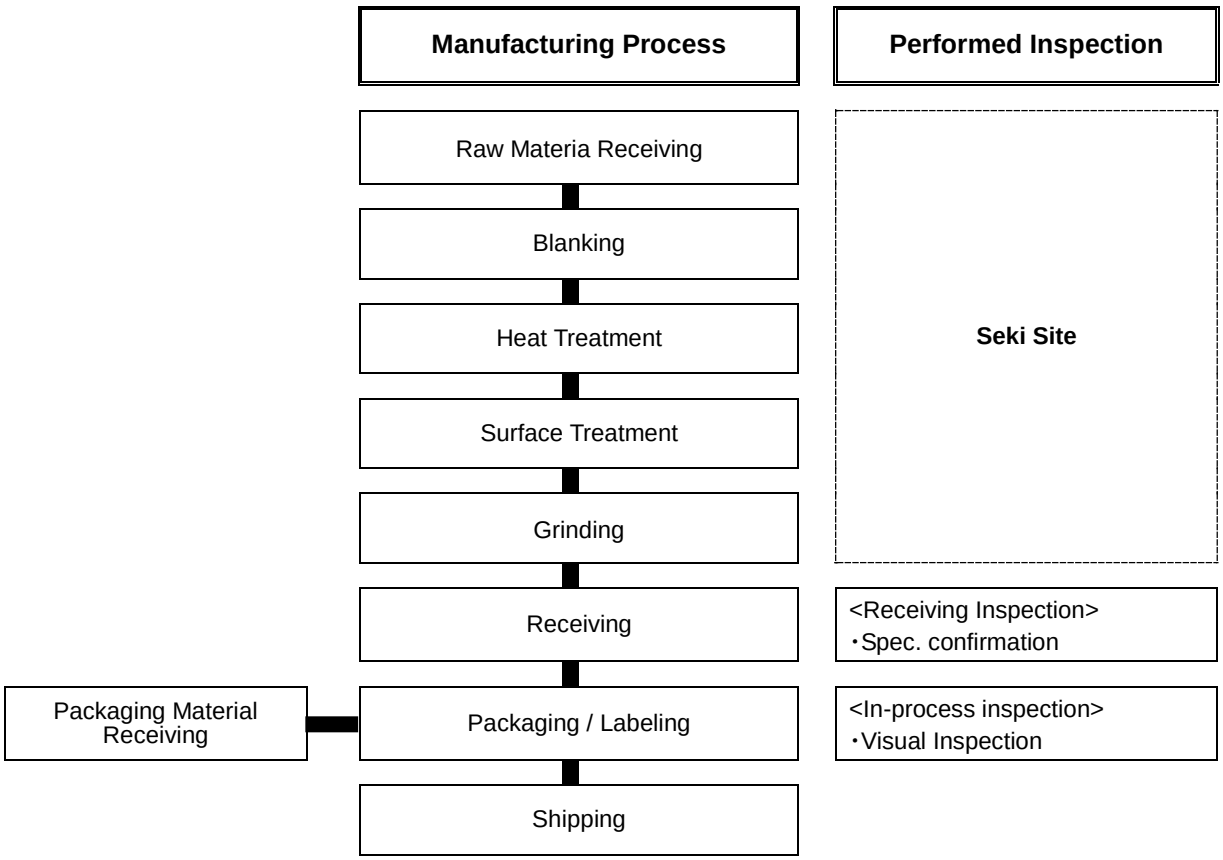
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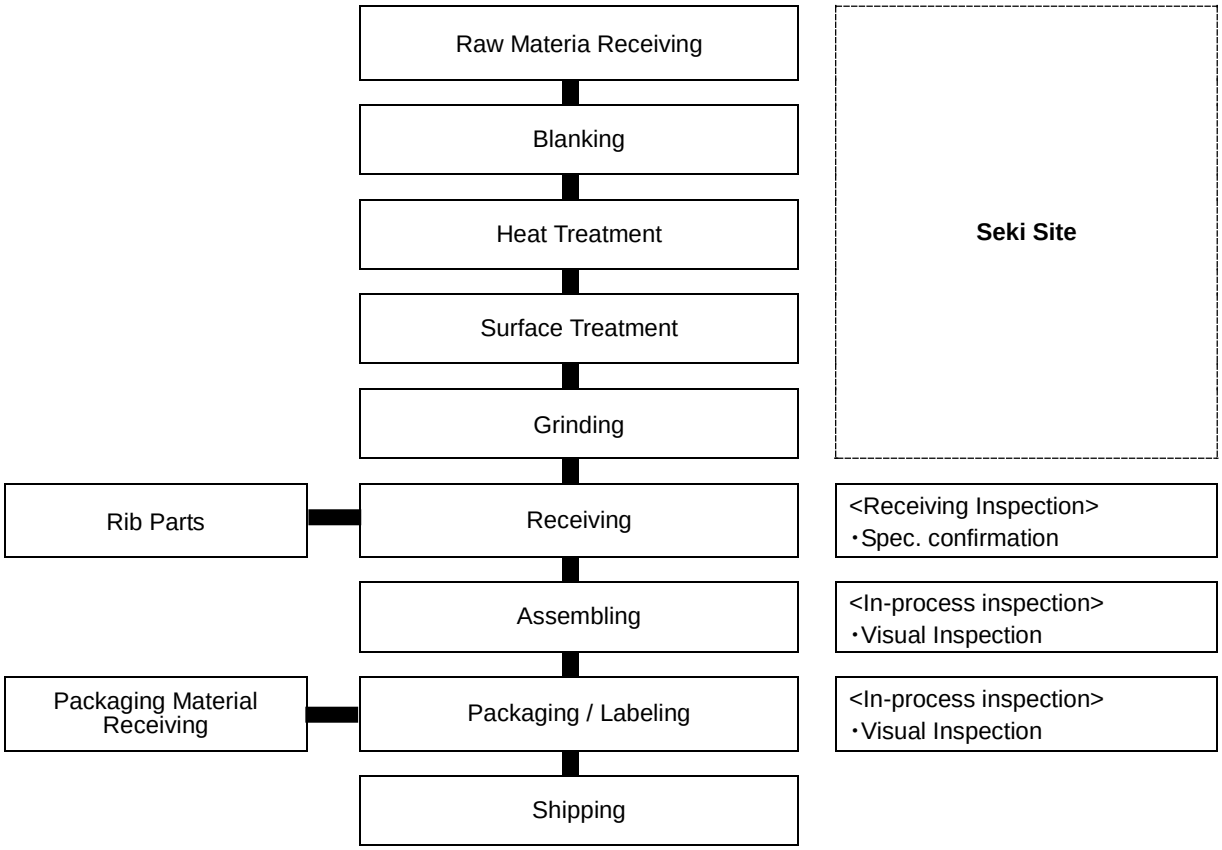
Components	Raw materials
BLADE	Carbon Steel
RIB(BLACK METAL)	Stainless steel
Individual package	Plastic case, Rust preventive paper
Sales unit package	Paper box

Intended purpose of use	**< FEATHER TRIMMING BLADE & SAFETY TRIMMING KNIFE BLADE >** **TRIMMING BLADES intended for cutting and trimming of the pathologic tissue or organ.**

TRIMMING BLADE



SAFETY TRIMMING KNIFE 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 TRIMMING BLADE** **FEATHER SAFETY TRIMMING KNIFE BLADE** *See attachment*
Standards applied	**ISO 13485:2003, ISO 14971:2007, EN 980:2008, EN 1041:2008**

Design	
Risk analysis	**Risk management report** **FEATHER TRIMMING BLADE** **FEATHER SAFETY TRIMMING KNIFE BLADE** *See attachment*
Labelling / IFU	**- Individual package** **- Sales unit package** *See attachment*
Product life	**NA**
Drawings:	
FEATHER TRIMMING BLADE	
No.130	**Drawing No. 8620000**
No.130R	**Drawing No. 8610003**
No.260	**Drawing No. 8630000**
FEATHER SAFETY TRIMMING KNIFE BLADE	
No.M130RC	**Drawing No. 8611003**
No.M260RC	**Drawing No. 8631003**

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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Change records

Date	Contents/details	Documentations	Contact to Notified body
2010/8/10	Integration of the technical document TDF_MD_06 / TDF_MD_10		
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.		