Technical Documents

File No. TDF_MD_04_Rev.11
Issued date; May 24, 2018

Category	**Scalpels & Blades**
Product group	**Disposable scalpels**
Product name	**FEATHER DISPOSABLE SCALPEL** **FEATHER DISPOSABLE SCALPEL DEEP** **FEATHER DISPOSABLE SCALPEL MINI** **FEATHER DISPOSABLE SCALPEL SAFESHIELD SCALPEL**
Certificate No.	**G1 17 06 57582 035**
GMDN codes	**Scalpel, single-use 47569**
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** **- Biocompatibility** **- Sterilization** **- Labeling / IFU** **- Product life** **- Result of bench testing** **- Clinical data** **- Drawings**
Change records	
Declaration of conformity	**F_Dec._MD_04 / F_Dec._MD_05 / F_Dec._MD_06 / F_Dec._MD_07**

Approved by; **Quality Control Dept.** **Quality Manager; KATSUHIKO KOMORI** **Signature**	**Author;** **Quality Control Dept.** **KENJI USAMI** **Signature**

DOMINIQUE DUTSCHER SAS

Product Description

General description of the devices

<FEATHER DISPOSABLE SCALPEL>

Components	Raw materials
BLADE	Stainless Steel - Blade material A: SANDVIK SV 13C26 - Blade material B: HITACHI Metals GIN5
HANDLE	AS
Individual package	Aluminum foil, Plastic film (Nylon)
Sales unit package	Sterile - Paper box

<FEATHER DISPOSABLE SCALPEL MINI>

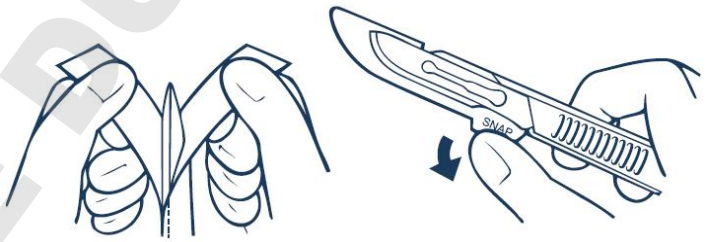
Components	Raw materials
BLADE	Stainless Steel - Blade material A: SANDVIK SV 13C26 - Blade material B: HITACHI Metals GIN5
HANDLE	ABS
Individual package	Aluminum foil
Sales unit package	Paper box

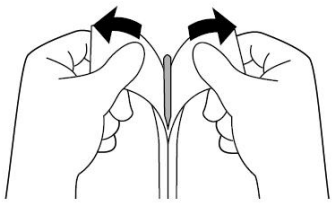
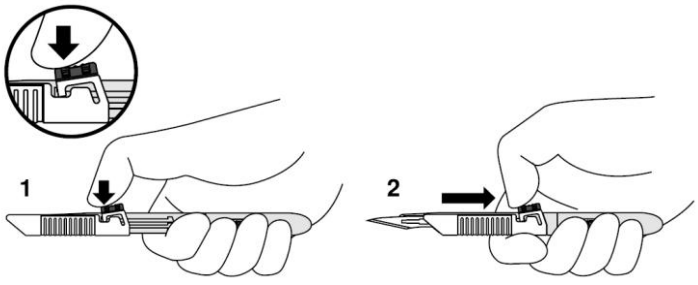
<FEATHERDISPOSABLE SCALPEL DEEP>

Components	Raw materials
BLADE	Stainless Steel - Blade material A: SANDVIK SV 13C26 - Blade material B: HITACHI Metals GIN5
HANDLE	AS
Individual package	Aluminum foil
Sales unit package	Paper box

DOMINIQUE DUTSCHER SAS

<table>
<tr>
<td>General description of the devices</td>
<td>
FEATHER DISPOSABLE SCALPEL SAFESHIELD SCALPEL

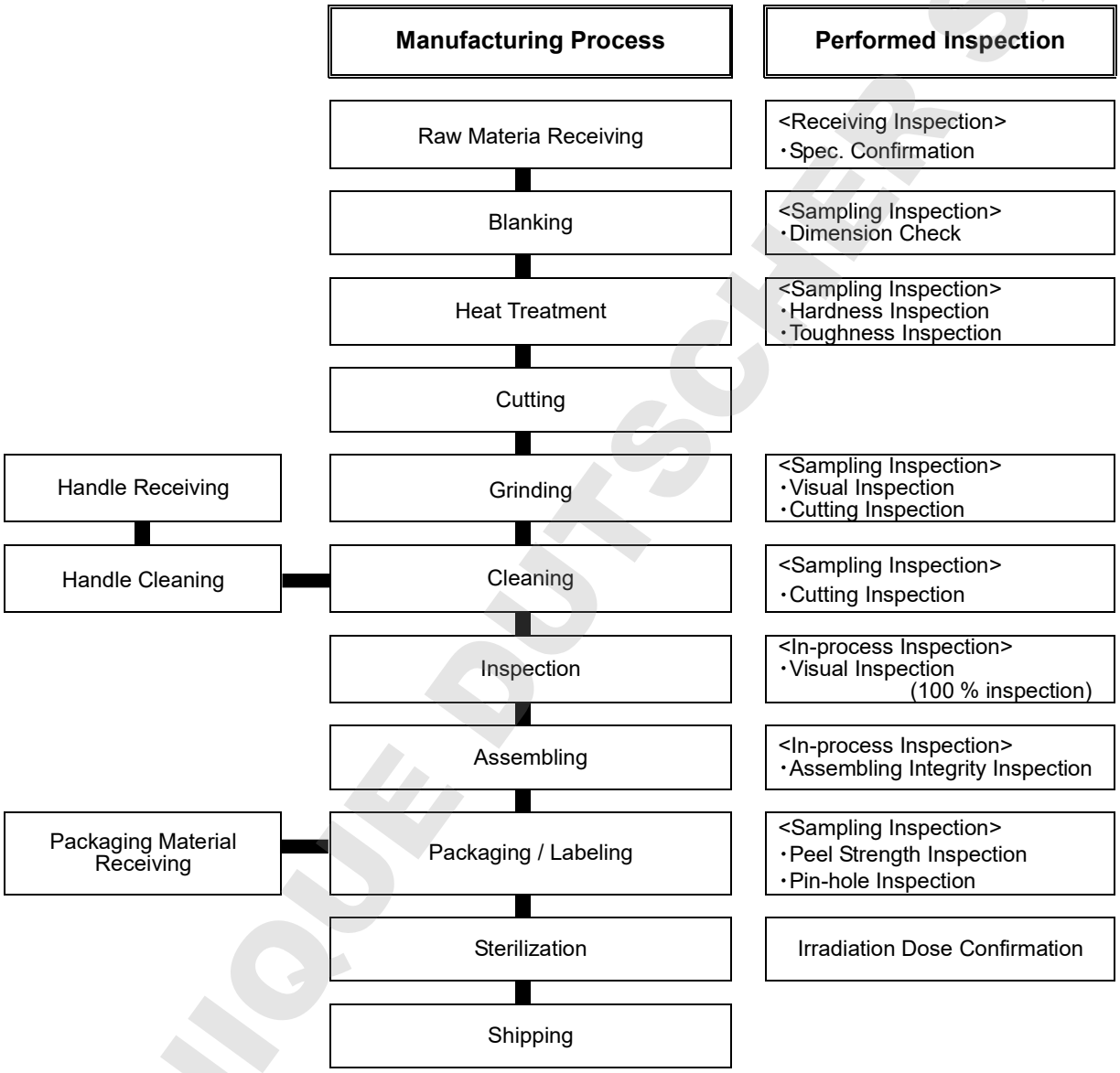
<table>
<tr><th>Components</th><th>Raw materials</th></tr>
<tr><td>BLADE</td><td>Stainless Steel
- Blade material A: SANDVIK SV 13C26
- Blade material B: HITACHI Metals GIN5</td></tr>
<tr><td>HANDLE</td><td>ABS</td></tr>
<tr><td>SAFTY COVER</td><td>ABS</td></tr>
<tr><td>Individual package</td><td>Polyethylene nonwoven fabric,
Plastic film (PET/PE)</td></tr>
<tr><td>Sales unit package</td><td>Paper box</td></tr>
</table>
※The stainless product is manufactured using either blade material A or B.
</td>
</tr>
<tr>
<td>Intended use</td>
<td>DISPOSABLE SCALPEL is intended for invasive operation, surgical incision and cutting for the human body (Skin, tissue, organ and etc.), it is transient use, and single use only.</td>
</tr>
<tr>
<td>Operation</td>
<td>
<DISPOSABLE SCALPEL, DEEP, MINI>


<FEATHER DISPOSABLE SCALPEL SAFESHIELD SCALPEL>



</td>
</tr>
</table>

DOMINIQUE DUTSCHER SAS

Manufacturing process



DOMINIQUE DUTSCHER SAS

Classification	**Device classification: IIa** **Based on the device's intended purpose of use, the device is "surgically invasive devices intended for transient use".** ***Decision making according to Annex IX, rule 6*** ***The device as* "surgically invasive devices intended for transient use" *is in class IIa because;*** - ***The device is not intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body. Therefore the device is not in class III.*** - ***The device is not reusable instruments. Therefore the device is not in class I.*** - ***The device is not intended specifically for use in direct contact with the central nervous system. Therefore the device is not in class III.*** - ***The device is not intended to supply energy in the form of ionizing radiation. Therefore the device is not in class IIb.*** - ***The device is not intended to have a biological effect or to be wholly or mainly absorbed. Therefore the device is not in class IIb.*** ***The device is not intended to administer medicines by means of a delivery system, or this is done in a manner that is potentially hazardous taking account of the mode of application. Therefore the device is not in class IIb.***

Technical requirements	
Identification of technical requirement	**Medical Device Directive 93/42/EEC** **Annex I Essential requirement**
Annex I checklist	**FEATHER DISPOSABLE SCALPEL** **FEATHER DISPOSABLE SCALPEL SAFESHIELD SCALPEL** *See attachment*
Standards applied	**EN ISO 13485:2012/AC:2012, EN ISO 14971:2012,** **EN ISO 10993-1:2009/AC:2010, EN ISO10993-18:2009,** **EN ISO 11137-1:2015, EN ISO 11137-2:2015,** **EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009, EN 980:2008,** **EN 1041:2008, EN ISO 11607-1:2009, EN ISO 11607-2:2006**

Design	
Risk analysis	**Risk management report** **FEATHER DISPOSABLE SCALPEL** **FEATHER DISPOSABLE SCALPEL SAFESHIELD SCALPEL** *See attachment*
Biocompatibility	**Biocompatibility evaluated in accordance with the ISO 10993-1** **BIOCOMPATIBILITY EVALUATION REPORT;** **FEATHER DISPOSABLE SCALPELS** *See attachment*

DOMINIQUE DUTSCHER SAS

Sterilization	**Sterilization method: Gamma irradiation** **Minimum dose 25kGy Maximum dose 60kGy**
Tests & Trials	**Dimensional check** **Hardness test** **Toughness test** **Cutting performance test** **Peel strength & open test**
Performance	**Sterility assurance level: 10^{-6}** **Cutting performance test result**
Labelling / IFU	**Individual package** **Sales unit package** *See attachment*
Product life	**5 years**
Result of bench testing	**Validation of sterilization report** **FEATHER DISPOSABLE SCALPEL** **FEATHER DISPOSABLE SCALPEL DEEP** **FEATHER DISPOSABLE SCALPEL MINI** **FEATHER DISPOSABLE SCALPEL SAFESHIELD SCALPEL** *See attachment*
Clinical data	**Clinical evaluation report** **FEATHER DISPOSABLE SCALPELS** *See attachment*

DOMINIQUE DUTSCHER SAS

Drawings:			
FEATHER DISPOSABLE SCALPEL		**SAFESHIELD SCALPEL**	
No.10	**Drawing No.9651002**	**No.10**	**Drawing No.5106001**
No.11	**Drawing No.9651102**	**No.11**	**Drawing No.5116001**
No.12	**Drawing No.9651202**	**No.14**	**Drawing No.5146001**
No.12d	**Drawing No.9650202**	**No.15**	**Drawing No.5156001**
No.14	**Drawing No.9651402**	**No.15C**	**Drawing No.5356001**
No.15	**Drawing No.9651502**	**No.20**	**Drawing No.5206001**
No.15c	**Drawing No.0200606**	**No.21**	**Drawing No.5206001**
No.20	**Drawing No.9652002**	**No.22**	**Drawing No.5226001**
No.21	**Drawing No.9652102**	**No.23**	**Drawing No.5236001**
No.22	**Drawing No.9652202**	**No.24**	**Drawing No.5246001**
No.23	**Drawing No.9652302**	**No.25**	**Drawing No.5256001**
No.24	**Drawing No.9652402**		
No.25	**Drawing No.9652502**		
FEATHER DISPOSABLE SCALPEL <DEEP>			
No.10	**Drawing No.9751010**		
No.11	**Drawing No.9751110**		
No.15	**Drawing No.9751510**		
No.20	**Drawing No.9752010**		
No.21	**Drawing No.9752110**		
No.22	**Drawing No.9752210**		
No.23	**Drawing No.9752310**		
FEATHER DISPOSABLE SCALPEL <MINI>			
No.11M	**Drawing No.9751105**		
No.14M	**Drawing No.9751405**		
No.15M	**Drawing No.9751505**		

DOMINIQUE DUTSCHER SAS

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**
Manufacturing facility **FEATHER SAFETY RAZOR CO., LTD.** **MINO SITE**	**Address** **600-1 Matsumori, Mino-City, Gifu 501-3753, Japan**
Design facility **FEATHER SAFETY RAZOR CO., LTD.** **RESEARCH & DEVELOPMENT CENTER**	**Address** **1-17, Hinode-Machi, Seki-City, Gifu, 501-3873 JAPAN**
Sterilization facility (Subcontractors) **RADIA INDUSTRIES CO., LTD.**	**Address** **168, Oyagi-cho, Takasaki-City, Gunma 370-0072, Japan**
EC-representatives **pfm medical ag**	**Address** **Wankelstraße 60, 50996 Cologne, Germany**
Notified body **TÜV SÜD PRODUCT SERVICE GmbH**	**Address** **Ridlerstraße 65, 80339 München, Germany**

DOMINIQUE DUTSCHER SAS

Change records

Date	Contents/details	Documentations	Contact to Notified body
2010/08/10	Integration of the technical document TDF_MD_08 / TDF_MD_09 TDF_MD_22 / TDF_MD_25		
2012/01/20	Specification in components of the devices.		
2013/04/01	Overseas trade division address change		Change notification
2014/11/01	Information for unsterile products have been deleted.		
2015/2/2	Description of packaging material has been matched with the design records.		
2015/8/17	R & D division address change.		
2015/12/26	Certificate No. has been updated. Performed inspection has been added to manufacturing process.		
2016/11/04	Description maintenance according to TD assessment.		
2017/3/23	Update of EC certificate number.		
2018/5/24	Update of EC certificate number and harmonized standard.		

DOMINIQUE DUTSCHER SAS