

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	1 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

RAZORMED SURGICAL BLADE CARBON STEEL STERILE SPECIFICATION

- 1.0 Standards:** Reference British Standard BS 2982 and ISO 7740 / EN 27740 and additional standards as identified and listed in Technical File.
- 2.0 Product Reference and Nomenclature of Carbon Steel Blades**
 Product References are listed in Part C of this document (Section 18).
 Nomenclature of various components and parts of sterile Carbon steel surgical blades are listed in Section 17: Drawing and Artwork Reference as per Technical File.
- 3.0 Raw Materials of Carbon Steel Surgical Blade:**
 Surgical carbon steel blades are manufactured from carbon steel conforming to British Standard specifications. Chromium percentage in excess of the standard of 0.6% is acceptable.
- 4.0 Marking of Carbon Steel Surgical Blades:**
 Carbon Steel Surgical Blades are stamped with Blade Size Number.
 Manufacturers Logo as required by BS 2982.
- 5.0 Outline Shape and Fitment of Carbon Steel Surgical Blades:**
 - 5.1 Outline Shape:**
 Are as listed in Section 17: Drawing and Artwork Reference as per Technical File.
 - 5.2 Fitment:**
 As per ISO 7740 / EN 27740.
 Handle Fitment No. 3 for blades of sizes 10,10A,10S, 11,11P,11K,11PA,12,12D,15,15C,15S
 Handle Fitment No. 4 for blades of sizes 18, 19, 20, 21, 22, 23, 24, 25,36
- 6.0 Hardness, Workmanship & Finish of Carbon Steel Surgical Blades:**
 - 6.1 Hardness:**

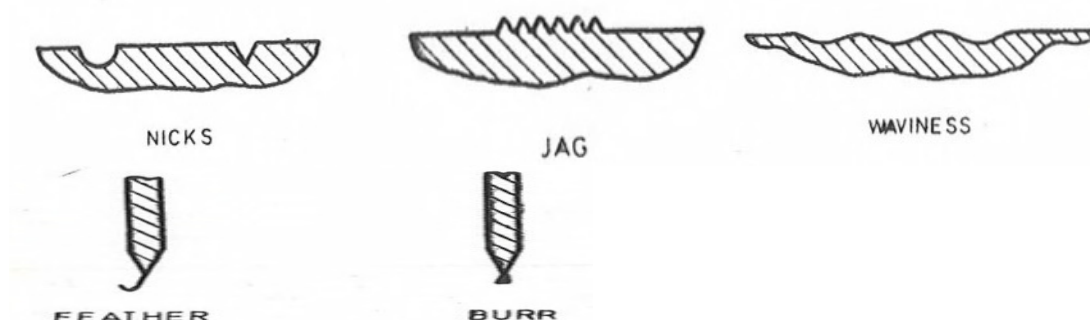
PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	2 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

Carbon steel surgical blades shall have a minimum hardness of 800 HV on the Vickers Scale.

6.2 Cutting Edge and Sharpness:

The central plane of the cutting edge shall be central with respect to the blade and, when inspected by normal or corrected vision, shall be free from nicks, burrs, waviness, feathered edges and jag. The cutting edge shall have an included angle not greater than 36 degrees. The two angles forming the included angle shall each be 13 ± 2.5 degrees.



6.3 Finish of Carbon Steel Surgical Blades:

When inspected by normal or corrected vision, the blade edges (except cutting edge) shall have a smooth finish and shall be free from burrs, pits, dents and without deep scratches (polishing brush marks are not considered defects). The stamping on the blade shall be deep enough for good legibility.

6.4 Freedom from extraneous matter:

Carbon Steel Surgical Blades shall be clean and free from extraneous matter like corrosion, oil, grease, and stains when inspected by normal or corrected vision. Slightly yellowish discoloration due to heat treatment or surface polishing is acceptable.

Carbon Steel Surgical Blades shall be free from inorganic and organic foreign particles on the product and on unit packs, as defined 6.4.1[(Ref. "Dirt estimation chart" (F-8.2.4-44)].

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	3 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

6.4.1. **Cleanliness** (Foreign particles) : Check through Dirt estimation Chart as shown below:

6.4.1.1 Inorganic loose foreign particle on the product (Not more than 0.2 mm in length)

6.4.1.2 Inorganic inbuilt foreign particle on the product (Not more than 1.0 mm in length)

6.4.1.3 Inorganic loose foreign particle on the unit pack (Not more than 2.0 mm in length)

6.4.1.4 Inorganic loose foreign particle inside the unit pack (Not more than mm1.0 in length)

6.4.1.5 Organic foreign particle Hair, Insects etc. (Not allowed)

7.0 Packaging: Configuration, Raw Materials, Marking and Labeling:

7.1. Configuration:

7.1.1 Unit container:

Except for blades made of stainless steel, the package shall contain a corrosion-inhibiting material. Each sterile blade shall be individually packed in a sealed container.

Note: The sealed container should be sufficiently robust to maintain the sterility of its contents under the conditions of handling and storage normally encountered in hospitals and medical practice.

7.1.2 Outer container:

Unit containers shall be packed in an outer container.

Note: The outer container shall be sufficiently robust to protect the contents during transit and storage.

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	4 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

In conformance of the above requirements of BS 2982, Razormed has developed the following packaging specifications:

7.1.3 Packaging of Carbon Steel Blades in Aluminum Foil Pack (unit container):

Carbon Steel Surgical blades are individually packed in aluminum foil laminate pack with white BRANOROST CR grade of anti-corrosive (VCI) paper on one inner side. The size of the top foil of pack is 87(L) x 27(W) mm and bottom foil is 90(L) x 27(W) mm. The foil pack has peel tab for easy and smooth opening of pack.

7.1.4 Packaging of Aluminum Foil Packs in a Unit Box (outer container):

Hundred (100) individually packed Carbon Steel Surgical blades are contained in a unit box of size 92 (L) x 65 (W) x 29 (H) mm.

7.1.5 Packaging of Unit Dispenser Boxes in Shelf Cartons:

Twenty (20) units of carbon steel surgical blade dispenser boxes are placed in a 3 ply Carton. The size of the 3 ply Carton is 315 mm (L) x 100 mm (W) x 140 mm (H).

7.1.6 Packaging of Cartons in Case:

Five (5) 3 ply Cartons containing 2000 carbon steel surgical blades are placed in a 5ply Case. The size of the Case is 535(L) x 335 (W) x 155(H) mm. Thus the total quantity in each Case is 100(Unit) x 20 (Unit box) x 5 (Shelf Carton) X 01(Case) = 10,000 blades.

Carton shall not be covered with polyethylene or any other covering

7.2 Material Specifications of Packaging Components

7.2.1 Material Specifications of Single Unit Foil Pack:

1. Aluminum Foil Layer 1:

30 + 6 % micron aluminum foil laminated with 30 ± 7.5 % micron milky white BOPP, printing with alcohol resistant Inks and protective coat on printing. This

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	5 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

aluminum foil laminated is specially developed packing material with excellent pin hole resistance and smooth opening without tear of any inner polymer layer. Material is Latex free.

2. Aluminum Foil Layer 2:

30 + 6% micron aluminum foil laminated with 30± 7.5 % micron transparent CPP, printing with alcohol resistant Inks and protective coat on printing. Material is Latex free.

3. Rust (Anti Corrosive) Inhibiting Paper

White BRANOROST CR grade of anti -corrosive (Volatile Corrosion Inhibitor) paper heat sealed to one inside layer of the unit foil pack.

7.2.2 Material Specifications of Unit Blade Dispenser Box:

Unit boxes are made of 400 gsm ±10% white coated board with grey or white back. 2 side flapped with tear-out dispensing aperture to the bottom right hand corner.

7.2.3 Material Specification of Cartons:

Cartons are made of 3 Ply structure. 2 Ply are 180 gsm virgin Kraft paper and 1 ply are 120 gsm semi-Kraft papers.

7.2.4 Material Specification of Case:

Case are made of a 5 Ply structure. 2 Ply are 180 gsm virgin Kraft paper and 3 ply are 250 gsm semi-Kraft papers. The Case has two broad flutes in corrugated structure.

7.3 Marking and Labeling of Unit Foil Pack

7.3.1 Unit pack artworks and labeling have been developed and approved as per the requirements. Top side of unit foil pack shall be printed in accordance with Artwork No. 297.

The following information is embossed on the bottom of the foil at the time of manufacture (Artwork No.229) :

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	6 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

LOT YYWWXXXX
EXP YYYY MM

The bottom foil also identifies the blade size of the contents.

7.3.2 Marking and Labeling of Unit Dispenser box:

Unit Box artworks and labeling instructions has been developed as per requirements. Artwork No. 296.

Each unit box will be labeled with the following 2 labels.

1. Tracking number bar code label (Artwork No.348)
2. Gamma irradiation label

7.3.3 Marking and Labeling of Shelf Cartons:

Each Carton will be labeled with Tracking Barcode label Artwork No. 166.

7.3.4 Marking and Labeling of Case:

The Case shall be labeled with Tracking Barcode Label: Artwork No.167.

8.0 Traceability of the Product:

Each product shall be embossed with the LOT and Expiry date.

LOT number is composed of the following information:

Year of Manufacturing (YY)
 Calendar week of Manufacturing (WW)
 Plan running number (XXXX)

Expiry date is denoted as YYYY MM.

Year of Manufacturing (YYYY)
 Month of Manufacturing (MM)

9.0 Environmental Controls and Product Bio-burden:

Surgical Carbon Steel Blades are packaged in clean room of class 8.
 The product bio-burden monitoring is done as per ISO 11737-1.

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	7 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

10.0 Sterilization Validation of Carbon Steel Surgical Blades:

Sterilization by gamma radiation to a minimum dosage of 25 kGy (2.5 Mrads). Sterilization process is validated in compliance with ISO 11137.

11.0 Shelf life of product :

5 years from date of sterilization.

12.0 No Exposure to Products with Rubber Latex:

Carbon steel surgical blades and its packaging are not made with natural rubber latex.

13.0 No Exposure to Products with Animal Origin

Carbon steel surgical blades are not exposed to any product or derivative of animal origin during manufacturing or packaging.

14.0 Risk Analysis:

These products have been evaluated for the requirements of ISO EN 14971 (Medical Devices - Application of Risk Management to Medical Devices).

15.0 Documents Required by Customer:

All shipping documents must have:

1. Invoice No. F 7.2 - 7
2. Packing List. Doc. Ref. No. F7.2-9C
3. Bill of Lading or AWB
4. Certificate of Origin GSP Form A
5. Irradiation Certificate
6. Analysis Certificate or CE Certificate of Conformity

16.0 Documents Required by Shipping Services Vendor:

1. Shipment Instruction
2. Airway bill / Bill of lading
3. GSP Declaration

17.0 Drawing and Artwork Reference as per Technical File.

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	8 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED & APPROVED BY	GENERAL MANAGER QA/RA & MR		

S.No.	DESCRIPTION	DRAWING/ARTWORK NOS.
1	Blade Size No.10	RMI-10-00-000DA
2	Blade Size No.10A	RMI-10A-00-000DA
3	Blade Size No.10S	RMI-10(S)-00-000DA
4	Blade Size No.11	RMI-11-00-000DA
5	Blade Size No.11K	RMI-11(K)-00-000DA
6	Blade Size No.11P	RMI-11P-00-000DA
7	Blade Size No.11PA	RMI-11PA-00-000DA
8	Blade Size No.12	RMI-12-00-000DA
9	Blade Size No.12D	RMI-12D-00-000DA
10	Blade Size No.15	RMI-15-00-000DA
11	Blade Size No.15C	RMI-15C-00-000DA
12	Blade Size No.15S	RMI-15(S)-00-000DA
13	Blade Size No.18	RMI-18-00-000DA
14	Blade Size No.19	RMI-19-00-000DA
15	Blade Size No.20	RMI-20-00-000DA
16	Blade Size No.21	RMI-21-00-000DA
17	Blade Size No.22	RMI-22(S)-00-000DA
18	Blade Size No.23	RMI-23-00-000DA
19	Blade Size No.24	RMI-24-00-000DA
20	Blade Size No.25	RMI-25-00-000DA
21	Blade Size No.36	RMI-36-00-000DA
22	Carbon steel foil packet	AW No. 297
23	Carbon steel Unit Box	AW No. 296
24	Lot Number & Exp date foil unit packet embossing	AW No. 229
25	Tracking Barcode Label for unit box	AW No. 348
26	Tracking Barcode Label for Shelf Carton	AW No. 166
27	Tracking Barcode Label for Case	AW No. 167
28	Consignor address Label for Case	AW No. 167
29	Back Foil designs	AW No.
	Blade shape printed foil for size No.10	AW No. 407

PRODUCT SPECIFICATIONS SHEET
RAZORMED BRAND SURGICAL BLADE CARBON STEEL STERILE FOR
PROCLINIC S.A.

DOCUMENT NO.	7.2.2PDS 1A	REVISION NO.	03
CUSTOMER	PROCLINIC S.A.	BRAND	RAZORMED
SPECIFICATION SERIAL NO.	100.34	SPECIFICATION REVISION NO.	00
PRODUCT TYPE	CARBON STEEL SURGICAL BLADE		
SPECIFICATION ISSUE DATE	07 FEBRUARY, 2013	PAGE NO:	9 OF 9
PREPARED BY	HOD QA/QC		
REVIEWED &	GENERAL MANAGER QA/RA & MR		
APPROVED BY			

Blade shape printed foil for size No.10S	AW No. 409
Blade shape printed foil for size No.11	AW No. 410
Blade shape printed foil for size No.11P	AW No. 413
Blade shape printed foil for size No.12	AW No. 415
Blade shape printed foil for size No.12D	AW No. 417
Blade shape printed foil for size No.15	AW No. 418
Blade shape printed foil for size No. 15C	AW No. 419
Blade shape printed foil for size No.15S	AW No. 420
Blade shape printed foil for size No.18	AW No. 421
Blade shape printed foil for size No.19	AW No. 422
Blade shape printed foil for size No.20	AW No. 423
Blade shape printed foil for size No.21	AW No. 424
Blade shape printed foil for size No.22	AW No. 425
Blade shape printed foil for size No.23	AW No. 427
Blade shape printed foil for size No.24	AW No. 428
Blade shape printed foil for size No.25	AW No. 429
Blade shape printed foil for size No.36	AW No. 430

18.0 References:

- 18.1 Razormed Technical File RMM 04.
- 18.2 Product Specification Sheet 7.2.2.PDS1 B
- 18.3 Product Specification Sheet 7.2.2.PDS1 C
- 18.4 Conformity Inspection Plan 8.2.4QAP.1