

<b>Name of the Manufacturer</b>	<b>RAZORMED INC.</b>
<b>Address of the Manufacturer</b>	B-3, Infocity, Sector 33-34, Gurgaon, Haryana, 122 001, India <b>Contact No.:</b> +91 124 433 8888 <b>Fax:</b> +91 124 433 8800 <b>Email ID:</b> info@razormed.com <b>Website:</b> www.razormed.com
<b>Registered Trademark</b>	
<b>SRN</b>	IN-MF-000012812
<b>Name of the Authorized Representative</b>	Advena Limited
<b>Address of the Authorized Representative</b>	Advena Limited, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>SRN</b>	MT-AR-000000234

**RAZORMED INC.** hereby under its own responsibility declares that the products covered within this declaration conform to the General Safety and Performance Requirements listed in Annex I of EU MDR (Regulation EU 2017/745). Supporting documentation in the form of the Technical File is retained under the premises of the manufacturer. This document contains both product-specific and process (Quality Management System) specific information.

**RAZORMED INC.** has its Quality Management System in place in compliance with EN ISO 13485:2016/A11:2021, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

<b>Applicable Harmonised Standards</b>	EN ISO 13485:2016/A11:2021 EN ISO 11137-1:2015/A2:2019 EN 10088-3:2014 EN ISO 11137-2:2015 EN ISO 13402:2000 EN ISO 10993-11:2018 EN ISO 10993-5:2009 EN 27740:1992/A1:1997 EN ISO 11607-1:2020 EN ISO 11607-2:2020 EN ISO 11737-2:2020 EN ISO 15223-1:2021 EN ISO 11737-1:2018/A1:2021 EN 868-5:2018 EN ISO 14971:2019/A11:2021 EN ISO 20417:2021 Full list of applicable standards, including non harmonised standards, are the part of technical file.
<b>Notified Body - Name</b>	Intertek Medical Notified Body AB
<b>Notified Body - Address</b>	Torshamn sgatan 43, Box 1103 SE-164 22 Kista Sweden
<b>Contact details of the Notified Body</b>	Phone: +46 8 750 00 00 Fax: +46 8 750 60 30 Email: IMNB@intertek.com

## DECLARATION OF CONFORMITY

<b>Notified Body - Number</b>	2862					
<b>Description of Conformity Assessment Procedure</b>	Regulation (EU) 2017/745 Annex IX Chapter I & III					
<b>Certificate No.</b>	28620140517					
<b>Validity of the certificate</b>	14 July 2027					
<b>Product Category</b>	Class IIa Surgical Instruments Class I Sterile devices Class I Reusable instrument					
<b>Products name, Classification, Rule, GMDN,EMDN codes and Basic UDI-DI.</b>	<b>Product name</b>	<b>Class</b>	<b>Rule</b>	<b>GMDN codes</b>	<b>EMDN Codes</b>	<b>Basic UDI-DI</b>
	Surgical Blades (Sterile & Non-sterile)	IIa	6	37445	V010302	8903376SBWT
	Disposable scalpels including safety types (Sterile & Non-sterile)	IIa	6	47569	V010101, V010102	8903376DSWG
	Dermal Curettes (Sterile & Non-sterile)	IIa	6	63259	A01020303	8903376DCVG
	Biopsy Punch (Sterile & Non-sterile)	IIa	6	63028	A01020302	8903376BPW4
	Stitch Cutter (Sterile)	Is	1	63487	V010301, V010302	8903376SCWV
	Reusable Handle (Non-Sterile)	Ir	1	12235	L010103	8903376RHX4
<b>MDN Code</b>	1208					
<b>MDS code(s)</b>	1005-4 and 1006					
<b>MDT code(s)</b>	2001, MDT 2002, MDT 2008 and 2011					
<b>Type of devices, Sizes and example Photographs</b>	Product List (Annex 1.1 of Technical File) DoC					
<b>Intended Purpose</b>	Product List (Annex 1.1 of Technical File) DoC					
<b>Brand Name</b>	Surgeon, Razormed, Diamantine, SAFhandle, Pic Solution, Securos, Derma-steel Fine, Salva, Taylor's, KENT Dental, R&S. Medibase, GIMA, Medlab.					

**RAZORMED INC.** states that the **Surgical Instruments** covered by the present declaration is in conformity with the Regulation EU 2017/745.

**Name:** Ambuj Srivastav

**Designation:** General Manager, QA/RA and MR

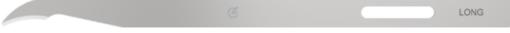
**Signature:** 

**Date:** 27.01.2023

Product List (Annex 1.1 of Technical File) DoC  
 Type of devices, Sizes and example Photographs.

Product Name	Type of Devices	Sizes	Product Image(example)
Surgical Blades (Sterile & Non-sterile).	Carbon Steel Surgical Blades	4, 6,8,9, 10, 10A, 10B, 10S, 10R, 11,11B,11K, 11PA, 11P, 12, 12A, 12B, 12D, 13,14, 15, 15A, 15B, 15C, 15S, 15T, 16, 17, 18,19, 20, 21, 22, 22A, 23, 24, 24D,	
	Stainless Steel Surgical Blades	25,25A, 27, 34, 36, 36D, 40, 60, 10SF, 15SF,18SF, 19SF, 20SF, 21SF, 22SF, 23SF, 24SF, 36SF, 10DM, 11DM,12DM, 12BDM, 15DM,15CDM, 18DM,19DM, 20DM, 21DM,22DM, 23DM, 24DM,25DM, 36DM,60DM, 10DS, 15DS, 18DS,19DS, 20DS, 21DS, 22DS, 23DS, 24DS, 36DS, 10OP, 11OP,12OP, 12BOP, 15OP, 15COP, 18OP, 19OP, 20OP, 21OP, 22OP, 23OP, 24OP, 25OP, 36OP, 60OP	
Disposable scalpels including safety types (Sterile & Non-sterile)  <i>The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures</i>	Standard Disposable Scalpels		
	Prima Std./Premium Disposable Scalpels		
	Prima/Premium Reinforced Disposable Scalpels		
	Classic Disposable Scalpels		
	Dental Disposable Scalpels		
	Mini Disposable Scalpels		
	Thumb Disposable Scalpels		
	Retractable Safety Scalpels with Steadfast Disposal Lock		
	Protective Shield Safety Scalpels with Steadfast Disposable Lock		

Product List (Annex 1.1 of Technical File) DoC  
Type of devices, Sizes and example Photographs.

			
<p>Dermal Curettes (Sterile &amp; Non-sterile)</p> <p><i>The intended purpose of Dermal curette is to make surgical scrapings or debridement of biological tissue required during surgical and other minor procedures</i></p>	....	2,3,4,5,7	
<p>Biopsy Punch (Sterile &amp; Non-sterile)</p> <p><i>The intended purpose of Biopsy punch is to remove a small section of dermal tissue, including its deeper layers (epidermis, dermis and superficial fat) via minimum damage to the surrounding tissue for histological examination during the biopsy procedure.</i></p>	....	From 0.50 mm to 12.0 mm, with 0.5 mm increment	
<p>Stitch Cutter (Sterile).</p> <p><i>The intended purpose of Stitch Cutter is to facilitate suture removal required during surgical procedures by cutting the suture stitches</i></p>	Carbon Steel Standard Stitch Cutter Blade	Stitch Cutter(SC), Stitch Cutter Long (SCL), Stitch Cutter Medium(SCM), Standard Stitch Cutter (SSC)	
	Carbon Steel Medium Stitch Cutter Blades		
	Carbon Steel Long Stitch Cutter Blades		
	Retractable Safety Stitch Cutter stainless steel blade with steadfast disposable lock.		

Product List (Annex 1.1 of Technical File) DoC  
 Type of devices, Sizes and example Photographs.

	Protective Safety Stitch Cutter Stainless Steel blade with steadfast disposable lock		
	Stainless Steel Stitch Cutter Blade		
	Stainless Steel Long Stitch Cutter Blade With Handle		
<p>Reusable Handle (Non-Sterile)</p> <p><i>Reusable Handle is intended for use as a compatible grip/hold of the surgical blade to perform surgical procedures using the blade</i></p>	<p>....</p>	<p>Fitment #3 and Fitment #4</p>	