



EC Declaration of Conformity
 according to the
 Medical Devices Regulation (EU) 2020/561 and 2017/745
Class I Medical Device
(non-sterile, without measuring function)

Manufacturer: **Rip Shears, LLC**

Address: 3432 Archer Ct
 Virginia Beach, VA 23452
 USA

EC Representative: Wellkang Ltd (www.CE-marking.eu)
 Enterprise Hub, NW Business Complex,
 1 Beraghmore Rd. **Derry**, BT48 8SE, **Northern Ireland, UK.**

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Type/model, identification of product allowing traceability (Where applicable)
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Please refer to attached list.

of class **Annex VIII – Classification**
Rules: Class I Medical Device
 (non-sterile, without measuring function)

is/are in conformity with the relevant provisions and essential requirements of Medical Devices Regulation (EU) 2020/561 and 2017/745.

Conformity assessment procedure **Annex X: Conformity Assessment Based On Type-Examination (Technical Documentation (Annex II) + EC Declaration of Conformity (Annex IV))**

Notified Body (name & number) **NOT applicable**

Certificate & number

Signed on: 1 January 2024. Place: Virginia Beach, VA, USA

Signature 

Name of authorized signatory: Christopher Freisenbruch
 Position held in the company: President

Product List

No	Product Name (Device/Make)	Model	Directive	Classification	GMDN Code	GMDN Term	Target Markets
1	Rip Shears	RS-1 Ripper	MDR	1	3752 1	Razor blade, accessory	Both EEA/EU27/NI & GB
2	Rip Shears	RS-2 Rip Shears (Black, Green, Tan)	MDR	1	1348 1	Bandage scissors, reusable, with accessory	Both EEA/EU27/NI & GB
3	Rip Shears	RS-3 Firefly Ripper	MDR	1	3752 1	Razor blade, accessory	Both EEA/EU27/NI & GB
4	Rip Shears	RS-3 Firefly Rip Shears (Firefly Orange, Nightlight Black)	MDR	1	1348 1	Bandage scissors, reusable, with accessory	Both EEA/EU27/NI & GB
5	Rip Shears	RS-4 Mini Rip Shears	MDR	1	1348 1	Bandage scissors, reusable, with accessory	Both EEA/EU27/NI & GB
6	Rip Shears	RS-5 Hook Knife	MDR	1	3752 1	Razor blade	Both EEA/EU27/NI & GB
7	Rip Shears	RS-6 Glass Break	MDR	1		Accessory	Both EEA/EU27/NI & GB
8	Rip Shears	RS-H Rip Shears Holster	MDR	1		Accessory	Both EEA/EU27/NI & GB
9	Rip Shears	RS Titanium Carbon Nitride (TiCN) Shears	MDR	1	1348 1	Bandage Scissors, reusable	Both EEA/EU27/NI & GB
10	Rip Shears	RS-B Ripper Replacement Blades	MDR	1	3752 1	Razor blade	Both EEA/EU27/NI & GB