



Expect Service

Radiation Products Design Inc

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CE 2024 SELF-DECLARATION OF CONFORMITY

Manufacturer's Name: Radiation Products Design, Inc.
Manufacturer's Address: 5218 Barthel Industrial Drive,
Albertville, MN, 55301 USA
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CE 2024 Technical File 936-583

Relevant EC Directives:

**Per Medical Device Directive (MDD) 93/42/EEC
Council Directive 2007/47/EC
Per Personal Protective Equipment (PPE)
Council Directive 89/686/EEC**

Equipment REF (Item) Numbers and Descriptions:

936-583: Tungsten Eye Shield, EXTRA SMALL, 2mm Thick with Aluminum Caps
936-585: Tungsten Eye Shield, SMALL, 2mm Thick with Aluminum Caps
936-587: Tungsten Eye Shield, MEDIUM, 2mm Thick with Aluminum Caps
936-589: Tungsten Eye Shield, LARGE, 2mm Thick with Aluminum Cap
936-591: Tungsten Eye Shield, EXTRA LARGE, 2mm Thick with Aluminum Caps
936-596: Tungsten Eye Shield, EXTRA SMALL, 3mm Thick with Aluminum Caps
936-598: Tungsten Eye Shield, SMALL, 3mm Thick with Aluminum Caps
936-601: Tungsten Eye Shield, MEDIUM, 3mm Thick with Aluminum Caps
936-623: Tungsten Eye Shield, LARGE, 3mm Thick with Aluminum Caps
936-627: Tungsten Eye Shield, EXTRA LARGE, 3mm Thick with Aluminum Caps
936-642: Tungsten Eye Shield 13.3mm I.D. x 2mm T. - No Stud
936-643: Tungsten Eye Shield 15mm I.D. x 2mm T. - No Stud
936-644: Tungsten Eye Shield 16.7mm I.D. x 2mm T. - No Stud
936-645: Tungsten Eye Shield 18.4mm I.D. x 2mm T. - No Stud
936-651: Tungsten Eye Shield 11mm I.D. x 3mm T. - No Stud
936-652: Tungsten Eye Shield 12.7mm I.D. x 3mm T. - No Stud
936-653: Tungsten Eye Shield 14.4mm .D. x 3mm T. - No Stud
936-654: Tungsten Eye Shield 16.1mm I.D. x 3mm T. - No Stud
936-655: Tungsten Eye Shield 17.8mm I.D x 3mm T. - No Stud

Equipment Description: Shields, Tungsten, Eye

The Tungsten Eye Shield can use either the 0.5 mm or 1 mm thick anodized aluminum cap (both are included with each tungsten eye shield) to reduce the electron backscatter to the eyelid. The eye shield can be used without the aluminum cap when placed superficially.

Non-sterile Product: The Product will arrive non-sterile. Sterilize before each new patient use. See Information/Instruction Booklet

FDA CFG Certificate Number: 76900-4-2024-1

FDA Registration Number: 2182762

FDA Classification: Class 1

GMDN Code and Term: 38361 Protection equipment, radiation, shield, eye

HIBCC UDI : G423

We herewith declare that the above-mentioned device/s, in view of its design and type of construction, meets the requirements of the above EC Directive.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid.

Signature:

Date: 6/06/2024



Printed Name: Howard D. Larson

Title: President

