Reinalmaging

PRODUCT DATASHEET

Model: PVDRNG14

Description: Mobile DR Panel Holder for 15x18" (35x43cm) Panels Revision: February 2018

PRODUCT ATTRIBUTES:

- Holds and protects DR Panel during exams and routine handling.
- Provides ergonometric handle on the short axis and double positive lock to secure DR Panel during transport.
- Made of shock absorbing materials.

MATERIAL COMPOSITION

| PART | MATERIAL | APPROXIMATE % |
|---------|--------------------|---------------|
| Shell | HDP | 98 |
| Overlay | Polycarbonate Film | 2 |

DIMENSIONS AND PERFORMANCE

Product Dimension: 21.4 x 15.4 x 0.9 in. (54.5 x 39.1 x 2.38 cm) Weight: 2.35 lbs. (1.07 kg) Weight Tolerance: 400 lbs. (181.4 kg) Not designed for weight bearing exams. Not to be used without an image receptor.

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FLAMMABILITY RATING

The product is non-flammable under the normal operating conditions of the DR Panel. UL Rating: UL94V-2.

BIOCOMPATIBILITY

This model is a biocompatible device per ISO 10993.

STATEMENT OF CONFORMANCE

Reina Imaging hereby states that the data, specifications, and descriptions contained herein this document are accurate and representative of the models being described.

REGISTRATIONS AND COMPLIANCE

All models listed above are made in the USA and registered to: Reina Imaging 6107 Lou Ave. Crystal Lake, IL 60014 USA

AUTHORIZED EU REPRESENTATIVE

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DEVICE FAMILY CLASSIFICATION

| Country | Class |
|---------|----------------------------|
| USA | FDA Class 1, 510(k) exempt |
| Canada | Class 1 |
| Europe | Class 1, Annex VII, CE |
| TGA | Class 1 |

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