



EU- Declaration of Conformity

issued under the sole responsibility of the manufacturer listed below:

| | |
|-----------------------------|--|
| Manufacturer's Name | Palmero Healthcare, LLC |
| Manufacturer's address/ SRN | 120 Goodwin Place, Stratford, CT 06615 USA |
| EU Representative Address | Hu-Friedy Europe LLC & Co. KG Bogenstrasse 6 – 8 78576 Emmingen - Liptingen Germany SRN: DE-AR-000005530 |
| Company Registered Number: | SRN: US-MF-000031389 |
| Quality System Cert No. | ISO 9001: CERT-0144026 PPE Module B: SH01258; PPE Module D: SH01125 |
| Notified Body No./Name | ISO 9001: SAI Global PPE: Shirley Technologies (Europe) Limited; #2895 |

As the manufacturer listed above, we declare that the devices listed:

| | |
|-------------------|--|
| Product(s): | See attached table |
| REF: | See attached table |
| Basic UDI-DI: | 0840415138355SP |
| Intended Purpose: | Palmero Dental X-Ray Aprons are used to protect the patient against x-ray radiation produced by imaging systems. |

meets all conformity requirements of the safety and performance requirements of the Medical Devices Regulation (MDR, Regulation (EU) 2017/745 as amended) and the Personal Protective Equipment Regulation (Regulation (EU) 2016/425 as amended).

Product classification according to the requirements described in **Annex VIII** of the Medical Devices Regulation, the medical device is assigned to risk **class 1** (conformity assessment per **Annex I, II, and III**) and **Risk Category III** as defined in **Annex I** of the PPE Regulation.

Core Materials Used: Cost Cruncher Lead; Scatter Sentry Lead-Free – 0.35mm Pb Lead Equivalence

Applied standards: ISO 9001, ISO 14971, ISO 15223-1, ISO 13688, EN 61331-1, EN 61331-3

Signed for and on behalf of Palmero Healthcare, LLC:

Signature: 

Name: Scott Philhower

Title: Sr. Manager, Regulatory Affairs

Place of Issue: Stratford, CT, USA

Date of Issue: 22 November 2023



| REF | Description | UDI DI |
|-----------------|---------------------------------------|----------------|
| 20AQUA-EU | PATIENT APRON AQUA EU | 00840415104838 |
| 20UAQUA-EU | PATIENT APRON UNLEADED AQUA EU | 00840415112680 |
| 20BEIGE-EU | PATIENT APRON BEIGE EU | 00840415112161 |
| 20UBEIGE-EU | PATIENT APRON UNLEADED BEIGE EU | 00840415112437 |
| 20BLUE-EU | PATIENT APRON BLUE EU | 00840415112185 |
| 20UBLUE-EU | PATIENT APRON UNLEADED BLUE EU | 00840415112451 |
| 20BURGUNDY-EU | PATIENT APRON BURGUNDY EU | 00840415113014 |
| 20UBURGUNDY-EU | PATIENT APRON UNLEADED BURGUNDY EU | 00840415113021 |
| 20GREY-EU | PATIENT APRON GREY EU | 00840415112178 |
| 20UGREY-EU | PATIENT APRON UNLEADED GREY EU | 00840415112444 |
| 20LIGHTGREY-EU | PATIENT APRON LIGHTGREY EU | 00840415112697 |
| 20ULIGHTGREY-EU | PATIENT APRON UNLEADED LIGHTGREY EU | 00840415112703 |
| 20MAUVE-EU | PATIENT APRON MAUVE EU | 00840415112710 |
| 20UMAUVE-EU | PATIENT APRON UNLEADED MAUVE EU | 00840415112727 |
| 20TEAL-EU | PATIENT APRON TEAL EU | 00840415112734 |
| 20UTEAL-EU | PATIENT APRON UNLEADED TEAL EU | 00840415112741 |
| 22AQUA-EU | CHILD'S APRON AQUA EU | 00840415112758 |
| 22UAQUA-EU | CHILD'S APRON AQUA EU | 00840415112765 |
| 22BEIGE-EU | CHILD'S APRON BEIGE EU | 00840415112123 |
| 22UBEIGE-EU | CHILD'S APRON UNLEADED BEIGE EU | 00840415112390 |
| 22BLUE-EU | CHILD'S APRON BLUE EU | 00840415112147 |
| 22UBLUE-EU | CHILD'S APRON UNLEADED BLUE EU | 00840415112413 |
| 22BURGUNDY-EU | CHILD'S APRON BURGUNDY EU | 00840415113038 |
| 22UBURGUNDY-EU | CHILD'S APRON UNLEADED BURGUNDY EU | 00840415113045 |
| 22GREY-EU | CHILD'S APRON GREY EU | 00840415112130 |
| 22UGREY-EU | CHILD'S APRON UNLEADED GREY EU | 00840415112406 |
| 22LIGHTGREY-EU | CHILD'S APRON LIGHTGREY EU | 00840415112772 |
| 22ULIGHTGREY-EU | CHILD'S APRON UNLEADED LIGHTGREY EU | 00840415112789 |
| 22MAUVE-EU | CHILD'S APRON MAUVE EU | 00840415112796 |
| 22UMAUVE-EU | CHILD'S APRON UNLEADED MAUVE EU | 00840415112802 |
| 22TEAL-EU | CHILD'S APRON TEAL EU | 00840415112819 |
| 22UTEAL-EU | CHILD'S APRON UNLEADED TEAL EU | 00840415112826 |
| 22SMILEY-EU | CHILD'S APRON SMILEY EU | 00840415112154 |
| 22USMILEY-EU | CHILD'S APRON LEAD FREE SMILEY EU | 00840415112420 |
| 24AQUA-EU | PROTECTALL APRON AQUA EU | 00840415112833 |
| 24UAQUA-EU | PROTECTALL APRON UNLEADED AQUA EU | 00840415112840 |
| 24BEIGE-EU | PROTECTALL APRON BEIGE EU | 00840415112093 |
| 24UBEIGE-EU | PROTECTALL APRON UNLEADED BEIGE EU | 00840415112369 |
| 24BLUE-EU | PROTECTALL APRON BLUE EU | 00840415112116 |
| 24UBLUE-EU | PROTECTALL APRON UNLEADED BLUE EU | 00840415112383 |
| 24BURGUNDY-EU | PROTECTALL APRON BURGUNDY NYLON EU | 00840415112659 |
| 24UBURGUNDY-EU | PROTECTALL APRON UNLEADED BURGUNDY EU | 00840415112857 |
| 24GREY-EU | PROTECTALL APRON GREY EU | 00840415112109 |
| 24UGREY-EU | PROTECTALL APRON UNLEADED GREY EU | 00840415112376 |



| REF | Description | UDI DI |
|-----------------|--|----------------|
| 24LIGHTGREY-EU | PROTECTALL APRON LIGHT GREY NYLON EU | 00840415112635 |
| 24ULIGHTGREY-EU | PROTECTALL APRON UNLEADED LIGHTGREY EU | 00840415112864 |
| 24MAUVE-EU | PROTECTALL APRON MAUVE EU | 00840415112871 |
| 24UMAUVE-EU | PROTECTALL APRON UNLEADED MAUVE EU | 00840415112888 |
| 24TEAL-EU | PROTECTALL APRON TEAL EU | 00840415112895 |
| 24UTEAL-EU | PROTECTALL APRON UNLEADED TEAL EU | 00840415112901 |
| 27AQUA-EU | CHILD'S PROTECT. APRON AQUA EU | 00840415112918 |
| 27UAQUA-EU | CHILD'S PROTECT. APRON UNLEADED AQUA EU | 00840415112925 |
| 27BEIGE-EU | CHILD'S PROTECT. APRON BEIGE EU | 00840415111850 |
| 27UBEIGE-EU | CHILD'S PROTECT. UNLEADED BEIGE EU | 00840415112321 |
| 27BLUE-EU | CHILD'S PROTECT. APRON BLUE EU | 00840415112079 |
| 27UBLUE-EU | CHILD'S PROTECT. UNLEADED BLUE EU | 00840415112345 |
| 27BURGUNDY-EU | CHILD'S PROTECT. APRON BURGUNDY EU | 00840415113052 |
| 27UBURGUNDY-EU | CHILD'S PROTECT. UNLEADED BURGUNDY EU | 00840415113069 |
| 27GREY-EU | CHILD'S PROTECT. APRON GREY EU | 00840415112062 |
| 27UGREY-EU | CHILD'S PROTECT. UNLEADED GREY EU | 00840415112338 |
| 27LIGHTGREY-EU | CHILD'S PROTECT. APRON LIGHTGREY EU | 00840415112949 |
| 27ULIGHTGREY-EU | CHILD'S PROTECT. APRON UNLEADED LIGHTGREY EU | 00840415112956 |
| 27MAUVE-EU | CHILD'S PROTECT. APRON MAUVE EU | 00840415112963 |
| 27UMAUVE-EU | CHILD'S PROTECT. APRON UNLEADED MAUVE EU | 00840415112970 |
| 27TEAL-EU | CHILD'S PROTECT. APRON TEAL EU | 00840415112987 |
| 27UTEAL-EU | CHILD'S PROTECT. APRON UNLEADED TEAL EU | 00840415112994 |
| 27SMILEY-EU | CHILD'S PROTECTALL APRON SMILEY EU | 00840415112086 |
| 27USMILEY-EU | CHILD'S PROTECTALL LEAD FREE SMILEY EU | 00840415112352 |
| 27HAPPYFACE-EU | CHILD'S PROTECT APRON HAPPYFACE EU | 00840415112628 |
| 27UHAPPYFACE-EU | CHILD'S PROTECTALL LEAD FREE HAPPYFACE EU | 00840415113007 |