



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

ANEXO II
DECLARACIÓN DE CONFORMIDAD INICIAL – PM CLASE I- II

Número de revisión: 235-267#0001

Número de PM:

235-267

Nombre Descriptivo del producto:

Pulidores para odontología

Código de identificación y nombre técnico UMDNS:

16-412- Pulidores

Clase de Riesgo:

Clase II

Marca de (los) producto(s) médico(s):

KENDA, COLTENE / WHALEDENT AG, DENT4YOU AG

Modelos (en caso de clase II y equipos):

KENDA Hybrid Pre-Polishers for Composites, Cup, RA.

KENDA Hybrid Pre-Polishers for Composites, Small Point, RA.

KENDA Hybrid Pre-Polishers for Composites, ShapeGuard, RA.

KENDA Hybrid Pre-Polishers for Composites, Point, RA.

KENDA Hybrid Pre-Polishers for Composites, Disc, RA.

KENDA Hybrid Pre-Polishers for Composites, Large Cup, RA.

KENDA Hybrid Polishers for Composites, Sample, RA.

KENDA Hybrid Diamond High Shine Polishers for Composites, Cup, RA.

KENDA Hybrid Diamond High Shine Polishers for Composites, Small Point, RA.

KENDA Hybrid Diamond High Shine Polishers for Composites, ShapeGuard, RA.

KENDA Hybrid Diamond High Shine Polishers for Composites, Point, RA.
KENDA Hybrid Diamond High Shine Polishers for Composites, Disc, RA.
KENDA Hybrid Diamond High Shine Polishers for Composites, Large Cup, RA.
KENDA Metals Pre-Polishers for Metals, Cup, RA.
KENDA Metals Pre-Polishers for Metals, Small Point, RA.
KENDA Metals Pre-Polishers for Metals, Point, RA.
KENDA Metals Pre-Polishers for Metals, Disc, RA.
KENDA All Ceramic Diamond Polishers for All Ceramics, Assortment, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Cup, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Coarse, Cup, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Small Point, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Coarse, Small Point, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Coarse, ShapeGuard, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Point, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Coarse, Point, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Disc, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Coarse, Disc, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Medium, Cup, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Medium, Small Point, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Medium, ShapeGuard, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Medium, Point, RA.
KENDA All Ceramic Diamond Pre-Polishers for All Ceramics, Medium, Disc, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Cup, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Fine, Cup, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Small Point, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Fine, Small Point, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Fine, ShapeGuard, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Point, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Fine, Point, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Disc, RA.
KENDA All Ceramic Diamond High Shine Polishers for All Ceramics, Fine, Disc, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, Sample, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, Assortment, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, Point, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, Cup, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, Small Point, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, ShapeGuard, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, Disc, RA.
KENDA Zirco1 Diamond Polishers for Zirconia and All Ceramics, Large Cup, RA.
KENDA Zircovis Diamond Polishers for Zirconia and All Ceramics, Assortment, RA.
KENDA Zircovis Diamond Pre-Polishers for Zirconia and All Ceramics, Cup, RA.
KENDA Zircovis Diamond Pre-Polishers for Zirconia and All Ceramics, Small Point, RA.
KENDA Zircovis Diamond Pre-Polishers for Zirconia and All Ceramics, Point, RA.
KENDA Zircovis Diamond High Shine Polishers for Zirconia and All Ceramics, Cup, RA.
KENDA Zircovis Diamond High Shine Polishers for Zirconia and All Ceramics, Small Point, RA.
KENDA Zircovis Diamond High Shine Polishers for Zirconia and All Ceramics, Point, RA.
KENDA Nobilis Diamond Polishers for Composite and Ceramic, Sample, RA.
KENDA Nobilis Diamond Polishers for Composite and Ceramic, Assortment, RA.
KENDA Nobilis Diamond Polishers for Composite and Ceramic, Large Flame, RA.
KENDA Nobilis Diamond Polishers for Composite and Ceramic, Small Flame, RA.
KENDA Nobilis Diamond Polishers for Composite and Ceramic, Knife, RA.

KENDA Nobilis Diamond Polishers for Composite and Ceramic, Cup, RA.
 KENDA Nobilis Diamond Polishers for Composite and Ceramic, Small Point, RA.
 KENDA Nobilis Diamond Polishers for Composite and Ceramic, ShapeGuard, RA.
 KENDA FG Series Diamond Pre-Polishers for Composites and Ceramics, Small Point, FG.
 KENDA Nobilis Diamond Polishers for Composite and Ceramic, Point, RA.
 KENDA Nobilis Diamond Polishers for Composite and Ceramic, Disc, RA.
 KENDA Nobilis Diamond Polishers for Composite and Ceramic, Large Cup, RA.
 KENDA Nobilis Diamond Polishers for Composite and Ceramic, Small Cup, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Sample, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Assortment, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Large Flame, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Small Flame, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Knife, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Cup, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Small Point, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, ShapeGuard, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Point, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Disc, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Large Cup, RA.
 KENDA Unicus Diamond High Shine Polishers for Composite and Ceramic, Small Cup, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Sample, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Assortment, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Large Flame, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Knife, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Cup, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Small Point, RA.
 KENDA FG Series Diamond High Shine Polishers for Composites and Ceramics, Small Point, FG.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, ShapeGuard, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Point, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Disc, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Large Cup, RA.
 KENDA Maximus 1-Step Diamond Polishers for Composite and Hybrid-Ceramic, Small Cup, RA.
 KENDA Deluxe Diamond Polishers for Composite and Hybrid-Ceramic, Sample, RA.
 KENDA Deluxe Diamond Polishers for Composite and Hybrid-Ceramic, Assortment, RA.
 KENDA Deluxe Diamond Pre-Polishers for Composite and Hybrid-Ceramic, Cup, RA.
 KENDA Deluxe Diamond Pre-Polishers for Composite and Hybrid-Ceramic, Small Point, RA.
 KENDA Deluxe Diamond Pre-Polishers for Composite and Hybrid-Ceramic, ShapeGuard, RA.
 KENDA Deluxe Diamond Pre-Polishers for Composite and Hybrid-Ceramic, Point, RA.
 KENDA Deluxe Diamond Pre-Polishers for Composite and Hybrid-Ceramic, Disc, RA.
 KENDA Deluxe Diamond Pre-Polishers for Composite and Hybrid-Ceramic, Small Cup, RA.
 KENDA Deluxe Diamond High Shine Polishers for Composite and Hybrid-Ceramic, Cup, RA.
 KENDA Deluxe Diamond High Shine Polishers for Composite and Hybrid-Ceramic, Small Point, RA.
 KENDA Deluxe Diamond High Shine Polishers for Composite and Hybrid-Ceramic, ShapeGuard, RA.
 KENDA Deluxe Diamond High Shine Polishers for Composite and Hybrid-Ceramic, Point, RA.
 KENDA Deluxe Diamond High Shine Polishers for Composite and Hybrid-Ceramic, Disc, RA.
 KENDA Deluxe Diamond High Shine Polishers for Composite and Hybrid-Ceramic, Small Cup, RA.

KENDA Complete Polishers for Composite/Compomer/Gold/Amalgam, Sample, RA.
 KENDA Complete Polishers for Composite/Compomer/Gold/Amalgam, Assortment, RA.
 KENDA Complete Pre-Polishers for Composite/Compomer/Gold/Amalgam, Cup, RA.
 KENDA Complete Pre-Polishers for Composite/Compomer/Gold/Amalgam, Point, RA.
 KENDA Complete Pre-Polishers for Composite/Compomer/Gold/Amalgam, Disc, RA.
 KENDA Complete Pre-Polishers for Composite/Compomer/Gold/Amalgam, Large Cup, RA.
 KENDA Complete High Shine Polishers for Composite/Compomer/Gold/Amalgam, Cup, RA.
 KENDA Complete High Shine Polishers for Composite/Compomer/Gold/Amalgam, Point, RA.
 KENDA Complete High Shine Polishers for Composite/Compomer/Gold/Amalgam, Disc, RA.
 KENDA Complete High Shine Polishers for Composite/Compomer/Gold/Amalgam, Large Cup, RA.
 KENDA Metals Polishers for Metals, Sample, RA.
 KENDA Metals Polishers for Metals, Assortment, RA.
 KENDA Metals Diamond High Shine Polishers for Metals, Cup, RA.
 KENDA Metals Diamond High Shine Polishers for Metals, Small Point, RA.
 KENDA Metals Diamond High Shine Polishers for Metals, Point, RA.
 KENDA Metals Diamond High Shine Polishers for Metals, Disc, RA.
 KENDA Planus Polishers for Acrylics, Assortment, RA.
 KENDA Planus Pre-Polishers for Acrylics, Large Flame, RA.
 KENDA Planus Pre-Polishers for Acrylics, Point, RA.
 KENDA Planus High Shine Polishers for Acrylics, Large Flame, RA.
 KENDA Planus High Shine Polishers for Acrylics, Point, RA.
 KENDA Precious Metals Pre-Polishers for Metals, Cup, RA.
 KENDA Precious Metals Pre-Polishers for Metals, Small Point, RA.
 KENDA Precious Metals Pre-Polishers for Metals, Point, RA.
 KENDA Precious Metals Pre-Polishers for Metals, Disc, RA.
 KENDA Precious Metals Diamond High Shine Polishers for Metals, Cup, RA.
 KENDA Precious Metals Diamond High Shine Polishers for Metals, Small Point, RA.
 KENDA Precious Metals Diamond High Shine Polishers for Metals, Point, RA.
 KENDA Precious Metals Diamond High Shine Polishers for Metals, Disc, RA.
 KENDA Amalgam Pre-Polishers for Amalgam, Large Flame, RA.
 KENDA Amalgam Pre-Polishers for Amalgam, Knife, RA.
 KENDA Amalgam Pre-Polishers for Amalgam, Cup, RA.
 KENDA Amalgam Pre-Polishers for Amalgam, Small Point, RA.
 KENDA FG Series Pre-Polishers for Metals, Small Point, FG.
 KENDA Amalgam Pre-Polishers for Amalgam, Point, RA.
 KENDA Amalgam High Shine Polishers for Amalgam, Large Flame, RA.
 KENDA Amalgam High Shine Polishers for Amalgam, Knife, RA.
 KENDA Amalgam High Shine Polishers for Amalgam, Cup, RA.
 KENDA Amalgam High Shine Polishers for Amalgam, Small Point, RA.
 KENDA FG Series High Shine Polishers for Metals, Small Point, FG.
 KENDA Amalgam High Shine Polishers for Amalgam, Point, RA.
 KENDA Nobilis & Unicus Polishers for Composite and Ceramic, Assortment, RA.
 KENDA Microfill Pre-Polishers for Composites, Large Flame, RA.
 KENDA Microfill Pre-Polishers for Composites, Knife, RA.
 KENDA Microfill Pre-Polishers for Composites, Cup, RA.
 KENDA Microfill Pre-Polishers for Composites, Small Point, RA.
 KENDA FG Series Pre-Polishers for Composites, Small Point, FG.
 KENDA Microfill Pre-Polishers for Composites, Point, RA.
 KENDA Microfill Pre-Polishers for Composites, Disc, RA.
 KENDA Microfill Pre-Polishers for Composites, Large Cup, RA.

KENDA Microfill Pre-Polishers for Composites, Small Cup, RA.
 KENDA Microfill High Shine Polishers for Composites, Large Flame, RA.
 KENDA Microfill High Shine Polishers for Composites, Knife, RA.
 KENDA Microfill High Shine Polishers for Composites, Cup, RA.
 KENDA Microfill High Shine Polishers for Composites, Small Point, RA.
 KENDA FG Series High Shine Polishers for Composites, Small Point, FG.
 KENDA Microfill High Shine Polishers for Composites, Point, RA.
 KENDA Microfill High Shine Polishers for Composites, Disc, RA.
 KENDA Microfill High Shine Polishers for Composites, Large Cup, RA.
 KENDA Microfill High Shine Polishers for Composites, Small Cup, RA.
 KENDA Prophy Polishers for Prophylaxis, Assortment, RA.
 KENDA Prophy Polishers for Prophylaxis, Cup, RA.
 KENDA Prophy Polishers for Prophylaxis, Small Point, RA.
 KENDA Prophy Polishers for Prophylaxis, Point, RA.
 KENDA Prophy Polishers for Prophylaxis, Large Cup, RA.
 KENDA Amalgam Polishers for Amalgam, Assortment, RA.
 KENDA Precious Metals Polishers for Metals, Assortment, RA.
 KENDA Microfill Polishers for Composites, Assortment, RA.
 KENDA Hybrid Polishers for Composites, Assortment, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Assortment, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse Assortment, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse, Large Flame, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Cup Assortment, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse, Cup, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Fine, Cup, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Medium, Cup, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, ShapeGuard Sample, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse, ShapeGuard, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Fine, ShapeGuard, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Medium, ShapeGuard, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse, Small Point, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Point Sample, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Point Assortment, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse, Point, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Fine, Point, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Medium, Point, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Disc Assortment, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse, Disc, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Fine, Disc, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Medium, Disc, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Large Cup Assortment, RA.
 KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Coarse, Large Cup,

RA.

KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Fine, Large Cup, RA.

KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Medium, Large Cup, RA.

KENDA C.G.I. Polishers for Composites, Compomers and Glass-Ionomers, Assortment, RA.

KENDA Zircovis Diamond Polishers for Zirconia and All Ceramics, Assortment, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, Super-Mix, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, Ass., RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, C, MiniCup, RA.

Polishette Diamond Polishers for Composite & Hybrid-Ceramics, Single-Use, F, MiniCup, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, M, MiniCup, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, Cup Sample, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, Cup Assortment, RA.

Polishette Mini Shaped Polishers for Composites and Hybrid-Ceramics, Single-Use, Cup-Mix, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, C, MiniPoint, RA.

Polishette Diamond Polishers for Composites & Hybrid-Ceramics, Single-Use, F, MiniPoint, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, M, MiniPoint, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, Assortment MiniPoint, RA.

Polishette Polishers for Composites and Hybrid-Ceramics, Single-Use, Point-Mix, RA.

ECO Line Polishers for Composites, RA, SET8000RA.

ECO Line Removers for Composites, RA, RE8005RA.

ECO Line Removers for Composites, RA, RE8008RA.

ECO Line Removers for Composites, RA, RE8009RA.

ECO Line Smoothers for Composites, RA, SM8005RA.

ECO Line Smoothers for Composites, RA, SM8008RA.

ECO Line Smoothers for Composites, RA, SM8009RA.

ECO Line Smoothers for Composites, RA, SH8005RA.

ECO Line Smoothers for Composites, RA, SH8008RA.

ECO Line Smoothers for Composites, RA, SH8009RA.

KENDA Queen Polishers for Acrylics. Assortment, HP.

KENDA Queen Polishers for Acrylics, Fine, Large Point, HP.

KENDA Queen Polishers for Acrylics, Fine, Rounded Cylinder, HP.

KENDA Queen Polishers for Acrylics, Fine, Large Bullet, HP.

KENDA Queen Polishers for Acrylics, Fine, Medium Point, HP.

KENDA Bestflex Polishers for Flexible Dentures, Assortment, HP.

KENDA Bestflex Polishers for Flexible Dentures, Large Point, HP.

KENDA Bestflex Polishers for Flexible Dentures, Rounded Cylinder, HP.

KENDA Bestflex Polishers for Flexible Dentures, Large Bullet, HP.

KENDA Bestflex Polishers for Flexible Dentures, Medium Point, HP.

KENDA Queen Polishers for Acrylics, Medium, Large Point, HP.

KENDA Queen Polishers for Acrylics, Medium, Rounded Cylinder, HP.

KENDA Queen Polishers for Acrylics, Medium, Large Bullet, HP.

KENDA Queen Polishers for Acrylics, Medium, Medium Point, HP.

KENDA Acrylic Blue Polishers for Acrylics, Assortment, HP.

KENDA Acrylic Blue Polishers for Acrylics, Very Coarse, Large Point, HP.

KENDA Acrylic Blue Polishers for Acrylics, Very Coarse, Rounded Cylinder, HP.

KENDA Acrylic Blue Polishers for Acrylics, Very Coarse, Large Bullet, HP.

KENDA Acrylic Blue Polishers for Acrylics, Very Coarse, Medium Point, HP.

KENDA Acrylic Blue Polishers for Acrylics, Medium, Large Point, HP.

KENDA Acrylic Blue Polishers for Acrylics, Medium, Rounded Cylinder, HP.

KENDA Acrylic Blue Polishers for Acrylics, Medium, Large Bullet, HP.

KENDA Acrylic Blue Polishers for Acrylics, Medium, Medium Point, HP.
KENDA Acrylic Blue Polishers for Acrylics, Extra Fine, Large Point, HP.
KENDA Acrylic Blue Polishers for Acrylics, Extra Fine, Rounded Cylinder, HP.
KENDA Acrylic Blue Polishers for Acrylics, Extra Fine, Large Bullet, HP.
KENDA Acrylic Blue Polishers for Acrylics, Extra Fine, Medium Point, HP.
KENDA Acrylic Blue Polishers for Acrylics, Assortment, HP.
KENDA Queen Polishers for Acrylics, Coarse, Large Point, HP.
KENDA Queen Polishers for Acrylics, Coarse, Rounded Cylinder, HP.
KENDA Queen Polishers for Acrylics, Coarse, Large Bullet, HP.
KENDA Queen Polishers for Acrylics, Coarse, Medium Point, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Small Wheel Assortment, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Coarse, Small Wheel, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Fine, Small Wheel, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Medium, Small Wheel, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Disc Assortment, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Coarse, Disc, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Fine, Disc, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Medium, Disc, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Coarse, Point, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Fine, Point, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Medium, Point, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Large Disc Assortment, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Coarse, Large Disc, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Fine, Large Disc, HP.
KENDA Z-Series Diamond Polishers for all types of Ceramics, Medium, Large Disc, HP.

Composición cuali-cuanti porcentual exacta (si corresponde):

No corresponde

Indicación/es autorizada/s:

Pulidores para uso en odontología.

Período de vida útil (si corresponde):

5 años

Método de Esterilización (si corresponde):

No corresponde

Forma de presentación:

Por 1 unidad, por 2 unidades, por 3 unidades, por 4 unidades, por 5 unidades, por 6 unidades, por 7 unidades, por 9 unidades, por 12 unidades, por 15 unidades, por 20 unidades, por 24 unidades, por 25 unidades, por 30 unidades, por 100 unidades.

Condición de uso:

Uso exclusivo a profesionales e instituciones sanitarias

Nombre del fabricante:

(1) Dent4You AG

(2) Coltene/Whaledent AG

Lugar/es de elaboración:

(1) Bahnhofstrasse 2, 9435 Heerbrugg, Suiza

(2) Feldwiesenstrasse 20, 9450 Altstätten, Suiza.

En nombre y representación de la firma DENTAL MEDRANO S.A. , el responsable legal y el responsable técnico declaran bajo juramento que los productos médicos enumerados en el presente Anexo, satisfacen los Requisitos Esenciales de Seguridad y Desempeño de Productos Médicos por la Disposición ANMAT N° 11467/24, que cumplen y se encuentra a disposición de la Autoridad Sanitaria la documentación técnica que contenga los requerimientos solicitados en el Apéndice IV y V del Anexo del Reglamento Técnico aprobado por Disposición ANMAT N° 64/25 y Disposición ANMAT N° 9688/19.

**CUMPLIMIENTO DE REQUISITOS ESENCIALES DE SEGURIDAD Y DESEMPEÑO.
DISPOSICIÓN ANMAT N° 11467/24 Y GESTIÓN DE RIESGO**

ENSAYO/VALIDACION/GESTION DE RIESGO	LABORATORIO /N° DE PROTOCOLO	FECHA DE EMISIÓN
I. Requerimientos Generales		
1. Aplica Directiva 93/42/ECC, ISO 13485:2012, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple	---	---
2. Aplica Directiva 93/42/ECC, ISO 13485:2012, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple	---	---
3. Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple	---	---
4. Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple	---	---
5. Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple	---	---
6. Aplica Directiva 93/42/ECC, ISO 13485:2019, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple	---	---
II. Requisitos Relativos al diseño y la fabricación		
7. Propiedades químicas, físicas y biológicas		
7.1 Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO	---	---

14971:2007, 90/385/EEC, 98/79/EC Cumple 7.2 Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple 7.3 Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple 7.4 Aplica Directiva 93/42/ECC, ISO 13485:2016, Cumple		
8. Infección y contaminación microbiana 8.1 Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple	---	---
8.2, 8.3, 8.4, 8.5 No aplica 8.6 Aplica Directiva 93/42/ECC, ISO 13485:2016, ISO 14971:2007, 90/385/EEC, 98/79/EC Cumple 8.7 No aplica	---	---
9. Construcción y propiedades ambientales 9.1, 9.2, 9.3 No aplica	---	---
10. Dispositivos con función de medición 10.1, 10.2 No aplica	---	---
11. Protección contra las radiaciones 11.1, 11.2, 11.3, 11.4, 11.5 No aplica	---	---
12. Requisitos para dispositivos médicos conectados o equipados con una fuente de energía 12.1, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8, 12.9 No aplica	---	---

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento mantener en su establecimiento y a disposición de la autoridad sanitaria la documentación allí declarada y la que establece la Disposición 9688/19, bajo apercibimiento de lo que establece la Ley N° 16.463, el Decreto N° 341/92 y las que correspondan del Código Penal en caso de falsedad.

En caso de inexactitud o falsedad de la información o documentación, la Administración Nacional podrá suspender, cancelar, prohibir la comercialización y solicitar retiro del mercado de lo ya autorizado e iniciar los sumarios que pudieran corresponder.

LUGAR Y FECHA: Argentina, 19 agosto 2025

Firmado digitalmente por:
CHAHBALIAN Liliana Claudia
Fecha y hora: 02.09.2025
11:59:48

Responsable Legal
Firma y Sello

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DE OLIVEIRA SILVA Tatiane
Fecha y hora: 02.09.2025
12:06:21

Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaria de Calidad en Salud
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 9688/19, quedando inscripta en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **DENTAL MEDRANO S.A.** bajo el número PM **235-267**

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad en la Ciudad de Buenos Aires a los días 19 agosto 2025 la cual tendrá una vigencia de cinco (5) años a contar de la fecha.



BODNAR Andrea Veronica
CUIL 27254978472

Dirección de Evaluación de Registro
Firma y Sello



TERRIZZANO Maria Lorena
CUIL 23242965604

Instituto Nacional de Productos Médicos
Firma y Sello



ABRIOLA Leticia Adriana
CUIL 27323186494



Código "N°rev legajo#version" vigente a partir de 07/02/22, reemplaza la anterior codificación.
La validez del presente documento deberá verificarse mediante el código QR.

Tramitada por Expediente N°: 1-0047-3110-005180-25-7



SCHUGURENSKY Gabriel Ernesto
CUIL 20201785767