THE DENTAL
SOLUTIONS
COMPANY™

Dentsply Sirona

Palodent® V3 Sectional Matrix System

EC Declaration of Conformity

Manufacturer's Name Address:	DENTSPLY Sirona 38 West Clarke Avenue Milford DE 19963 USA
Authorized EC Representative Name and Address:	DENTSPLY DeTrey GmbH DeTrey Strasse 1 Konstanz Germany D-78467
Unique Product Identification:	659700v Palodent® V3 Sectional Matrix System Introductory Kit 659710v Palodent® V3 Sectional Matrix System 3.5mm Matrix Bands Refill 659720v Palodent® V3 Sectional Matrix System 4.5mm Matrix Bands Refill 659730v Palodent® V3 Sectional Matrix System 5.5mm Matrix Bands Refill 659740v Palodent® V3 Sectional Matrix System 5.5mm Matrix Bands Refill (100ct) 659750v Palodent® V3 Sectional Matrix System 6.5mm Matrix Bands Refill 659760v Palodent® V3 Sectional Matrix System Universal Rings Refill 659770v Palodent® V3 Sectional Matrix System Narrow Rings Refill 659780v Palodent® V3 Sectional Matrix System Small Wedges Refill 659790v Palodent® V3 Sectional Matrix System Medium Wedges Refill 659800v Palodent® V3 Sectional Matrix System Large Wedges Refill 659810v Palodent® V3 Sectional Matrix System Forceps 659820v Palodent® V3 Sectional Matrix System Pin Tweezers 659830v Palodent® V3 Sectional Matrix System Small Wedge Guard Refill 659840v Palodent® V3 Sectional Matrix System Medium Wedge Guard Refill 659850v Palodent® V3 Sectional Matrix System Large Wedge Guard Refill 659860v Palodent® V3 Sectional Matrix System 7.5mm Matrix Bands Refill 659900v Palodent® V3 Sectional Matrix System Ring Refill 625.00.005 Palodent® V3 Starter Kit
Description:	The Palodent® V3 Sectional Matrix System employs a Nickel-Titanium retaining ring, interproximal wedge, wedgeguard and sectional matrices for placement of restorations in the posterior region. Sectional matrices are suitable for use with all posterior restorative materials. The retaining rings are available in narrow, for most premolar and small molars or universal, for larger molars. Rings may be used either singly or in tandem, for simultaneous restoration of multiple surfaces. The advantages of the sectional matrices and rings include natural contours for better control of contact areas and embrasures, ease of placement, better visualization of the operative field, and more comfort for the practitioner and patient. Eliminating the leverage of a conventional matrix retainer allows the practitioner to use less tension, avoiding excessive compression of tooth and easier formation of anatomical proximal contact areas. When placed prior to preparation, the innovative Wedgeguard combination wedge and shield protects approximating surfaces from inadvertent damage during preparation. Using the pin tweezers, the shield easily slides away, leaving the wedge securely in place.
GMDN Code:	P38786 – Dental matrix band, single use P45007 – Dental wedge, single use P45008 – Dental matrix band tensioner P35851 – Rubber Dam clamping forceps P31814 – Dental Dressing forceps

Product Classification Per Annex IX:	**This product is classified as a Class I Medical Device under Annex IX Section III, rule 5, transient, invasive device.**

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The above listed medical device(s) conform to the requirements of Council Directive 93/42/EEC *as amended by Council Directive 2007/47/EC* and meet the relevant Essential Requirements of Annex I. All devices are designed, manufactured, tested, and released for sale in accordance with the technical documentation.

DENTSPLY Sirona maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820 & 211, ISO 13485:2003, CMDR, PMDL (MO 169) and the European Union Council Directive 93/42/EEC.

Authorized Signature:

Name: _____ **Date of Issuance:** October 6, 2017

Karen Trovalli
QA/RA Manager