### PRODUCT INDICATION

**Product type**
- Lateral flow rapid test

**Indication**
- The product detects elevated levels of the collagenase, aMMP-8 (active matrix metalloproteinase-8), an enzyme that destroys tissue, in oral lavage fluid.
- If detected in time, the development of periodontitis can usually be halted and existing periodontitis successfully treated by a dentist or periodontist in cooperation with a dental hygienist or dental assistant.

### PRODUCT PROPERTIES

**Origin**
- dentognostics GmbH, Tatzendpromenade 2, 07745 Jena, Germany

**Storage temperature**
- 2°C – 25°C

**Product specifications**
- The PerioSafe® tests should be administered by the dental assistant or hygienist as the first thing immediately when the patient sits in the dental chair. There should be no treatment or activity in the mouth before the test.
- Patients should avoid eating, drinking anything but water, smoking, using mouthwash, or brushing their teeth for at least 20 minutes before the test. If they have eaten, then they should rinse with water and then wait at least 60 seconds for the saliva to return to the mouth before proceeding with the sample collection.
- The PerioSafe® test is meant to be used to screen generally healthy looking patients or patients in a recall phase after periodontal treatment. It is not indicated to use on patients with acute periodontitis. For these patients, the PerioSafe® POOL test should be used instead.
- Retesting should occur no sooner than 2 weeks after basic preventive treatments and no sooner than 6 weeks after periodontal therapy.

**Component Parts**
- **1. Test cassette:** for applying a sample and displaying the test result [REF 32501ETDE aMMP-8 Test]
- **2. Rinsing solution:** of purified water for obtaining samples [REF 32505ETDE Purified Water 5 ML CE0459]
- **3. Cup:** for holding rinsing solution and catching the sample [REF 32508ETDE Cup]
- **4. Syringe:** for applying the sample to the test cassette [REF 32507ETDE SoftJect®]
- **5. Filter:** for mounting on the syringe and to filter the sample BEFORE applying to the test cassette [REF 32506ETDE Filter Acrodisk 25 MM]
- **6. QR Code:** on the outside of packaging [REF 960-00104]
- **7. Short instructions:** with the pictograms
- **8. Instructions for use:** detailed information on the test

**Sterilization / Disinfection**
- The product is aseptically manufactured and sterile
- The product is for single use only

**Shelf life**
- 18 months

**Regulatory status**
- In vitro diagnostic device (IVD) with CE mark

**Entry on the market**
- 2010
### AVAILABLE PRODUCT LINE

<table>
<thead>
<tr>
<th>Product</th>
<th>Type/Size/Amount</th>
<th>Art.-No.</th>
</tr>
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<tbody>
<tr>
<td>PerioSafe®/ImplantSafe® DR</td>
<td>25 Tests</td>
<td>970-00225</td>
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<tr>
<td>PerioSafe®/ImplantSafe® DR</td>
<td>50 Tests</td>
<td>970-00250</td>
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<tr>
<td>PerioSafe®/ImplantSafe® Pool DR</td>
<td>25 tests</td>
<td>970-00325</td>
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<tr>
<td>PerioSafe®/ImplantSafe® Pool DR</td>
<td>50 tests</td>
<td>970-00350</td>
</tr>
<tr>
<td>ORALyzer®</td>
<td>complete, incl. Drawer 4&amp;5, Printer</td>
<td>970-00001</td>
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<td>Drawer for PerioSafe® PRO DRS</td>
<td>1 drawer</td>
<td>970-00005</td>
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<tr>
<td>Drawer for PerioSafe®/ImplantSafe® DR</td>
<td>1 drawer</td>
<td>970-00007</td>
</tr>
</tbody>
</table>

### HOTLINE

- **UK:** (+44) 01 296 653230
- **Italy:** (+39) 800 810 500
- **Germany:** (+49) 761 450 13 50

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