DIRECTA

# EU Declaration of Conformity - PractiPal®

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|---|---|
| **Manufacturer** | **DIRECTA AB**<br>Finvids väg 8, SE-194 47 Upplands Väsby, Sweden |
| **SRN** | SE-MF-000002500 |
| **Basic UDI-ID** | 731023999515AX |

| **Product/trade name** | **Product code/REF** |
|---|---|
| PractiPal® Tray | 115100 |
| PractiPal® Mini Tray | 115020 |
| PractiPal® Instrument Clamp | 115150, 115151, 115152, 115153, 115154, 115155, 115156, 115157, 115158 |
| PractiPal® Mini Clamp | 115040, 115041, 115042, 115043, 115044, 115045, 115046, 115047, 115048 |
| PractiPal® Compact Bur Stand | 115185, 115186, 115187, 115188, 115189, 115121, 115122, 115123, 115124 |
| PractiPal® Compact File Stand | 115180, 115181, 115182, 115183, 115184, 115176, 115177, 115178, 115179 |
| PractiPal® MultiBlock | 115140, 115141, 115142, 115143, 115144, 115145, 115146, 115147, 115148 |
| PractiPal® MultiDappen | 115000 |
| PractiPal® MultiPoint | 115001 |
| PractiPal® Waste Cup | 115002 |
| PractiPal® Foam | 115003, 115004 |
| PractiPal® Bur/Endo Stand | 115130, 115131, 115132, 115133, 115134, 115135, 115136, 116137, 115138 |
| **PractiPal® Kits** | |
| Tray/Instrument Clamp | 115110, 115111, 115112, 115113, 115114, 115106, 115107, 115108, 115109 |
| Mini Tray/Mini Clamp | 115050, 115051, 115052, 115053, 115054, 115055, 115056, 115057, 115058 |
| Compact Bur Set | 115160, 115161, 115162, 115163, 115164, 115170, 115171, 115172, 115173 |
| Compact File Set | 115200, 115201, 115202, 115203, 115204, 115205, 115206, 115207, 115208 |
| Complete set | 115191, 115192, 115193, 115194, 115195, 115196, 115197, 115198, 115199 |

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| **Intended purpose** | A system combined of trays and modules for dental instrument handling at dental clinics. The system organizes the handling of instruments, burs and root canal files during treatment, reprocessing and storing.<br>Disposable to keep liquid or other substances, to hold points, for waste and to hold and clean files.<br>Bur/Endo stand also used as a gauge/gives references to endodontic measurements during endodontic treatment.<br>Intended users are dentists, dental hygienists and dental assistants. |
| **Risk Class** | Class I, rule 1 |
| **Common specification (CS)** | N/A |
| **Notified body** | N/A |
| **Conformity Assessment Procedure** | Article 52, paragraph 7<br>Annex II and III |
| **Statement** | We, Directa AB, confirm that this EU declaration of conformity is issued under our sole responsibility and that the device covered by this declaration is in conformity with Regulation (EU) 2017/745 on medical devices. |

Upplands Väsby, 2021-08-31

Henric Karsk
CEO

*First version of EU Declaration of Conformity (MDR) issued year 2021.*
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