# Related Test Specification

|  |  |
| --- | --- |
| Filename | QUF73-2484 Template Test Specification (vx.y) |

|  |
| --- |
| Final Result |
| Pass  Passwith deviations  Fail |

# Test Environment

*< for V&V in design or equipment validation only 🡪 describe details on the test environment in this document (reference objective evidence) or create an additional document; when you use equipment controlled within the QMS that your details given correspond to the entry in the respective list >*

Location:

Products and accessories used:

|  |  |  |
| --- | --- | --- |
| **Article No.** | **Article** | **SN/Charge/LicenseNo.** |
| 6000-1 | Dental Wings Intraoral Scanner Starter Kit (DW-IO-001 including standard and optional articles listed below) | Type/Model: type/model from name plate  SN: serial number from nameplate  Handpiece serial number: serial no. from handpiece  Intraoral scanner software: version  Handpiece firmware: version  Handpiece control unit firmware: version  Master Harddisk: version |
| 22-0156 (US)  22-0159 (EU) | Country-specific Power Cord | Keep only the correct article number |
| 30-0126 | Integrity-Check Tool | n/a |
| 40-0131 | Reprocessing Station | Not shipped. Not required for testing. |
| 312105-0008, from ThermoScientific Nalgene (19-0046) | Reprocessing Bottle | Not shipped. Not required for testing. |
| 70-0045 | Handpiece Storage Case | n/a |
| 70-0040 | Shipping box | n/a |
| 400.200 from Dentaco | ScanLiquid, from Dentaco | Not shipped. Not required for testing. |

Equipment used:

|  |  |  |
| --- | --- | --- |
| **Plaster Model** | **ID & picture** | **Details related to the reference scan**  **Scanned with (give manufacturer; type/model; serial number; accuracy statement of manufacturer):.** |
| plaster model with tooth stump (used e.g. for crowns) |  | Reference to STL file of scan: where to be found & controlled  Reference scan taken on yyyy-month-dd with:   * Scanner Manufacturer: manufacturer * Type//Model: type/model as given on name plate * SN: serial number * Accuracy statement from user manual p. x: statement |

|  |  |
| --- | --- |
| **Type** | **ID and / or description** |
| PC | <main characteristics> |

*<For validated equipment ID is sufficient, same for specific tools if they are listed in the respective overiew lists>*

Measurement Equipment used:

*<only required when the preciseness of a value is of importance, not e.g. for weight given in the user manual or shipping documentation>*

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **ID** | **Manufacturer** | **Last Calibration Date** |
| Balance |  |  |  |

Test participants: Martin Carufel / MC

# Test Results

| Step | Result Description | Result (Pass or Fail  (P/F)) | Test Date (yyyy-mm-dd) | Initials |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

# Referenced Documents

*<if applicable, otherwise delete section>*

1. *<ID title (version) or approval date >*
2. DEX73-2686 DWIO Validation Test Report UC\_001 UC\_002 (v1.0)
3. …
4. …

*<Note: Version numbers or dates for documents reviewed are mandatory for test reports, since we do not want to deliver DHF or DMR to authorities, only a selection of certain reports which need to have the same version information as the test report shows.>*

# Deviations

| Step | Deviation Description | Is fixing and retest necessary? (yes / no) | If no: Risk Assessment | Must end-user be informed? (yes/no) | Initials |
| --- | --- | --- | --- | --- | --- |
| n/a | n/a | n/a | n/a | n/a | n/a |

# Summary and Conclusion

# Appendix

*<if applicable, otherwise delete section>*