| **Manufacturer:** | Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands
SRN: NL-MF-000001489 |

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Object of the declaration:

| **Product Name**: | IntelliSpace Portal |

| **Intended Use:** | The IntelliSpace Portal processes clinical images from different modalities and enables advanced visualization of the images. When used by qualified personnel, it provides useful diagnostic information. IntelliSpace Portal can be used remotely by multiple users with compatible devices. |

| **Medical Device Identification** | IntelliSpace Portal V12.1 |

| **UDI-DI:** | 00884838093621 |

| **Basic UDI-DI:** | NA |

| **Control Indicator/LOT:** | 12.1 |

| **GMDN code:** | 57812 |

Device configuration list:

Model Description	Model Number
IntelliSpace Portal Solutions	881001/881101
IntelliSpace IX/LX Workstation	881030/881103
Upgrades IntelliSpace Portal	881011/881102
Upgrades IntelliSpace IX/LX Workstations	881033/881104

The object of the declaration described above is in conformity with the following:

| **EU Directive** | **Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and amendments** |
| **Device Risk Classification** | Class IIa
based on Annex IX rule 10 |

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Effective: 30-Nov-2019

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Conformity Assessment Procedure	Annex II excluding (4) The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II of the Medical Device Directive 93/42/EEC and amendments. Copies of the QS certificates are available upon request.
Name/Address/ID of Notified Body	TÜV Rheinland LGA Products GmbH Tilllystrasse 2, 90431 Nürnberg, Germany Identification Number: 0197
Starting Date:	March 2021
Harmonised Standards	The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are compliant with the standards listed below.

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 62304:2006 +A1:2015 EN 62304:2006 EN 62304:2006/AC:2008	Medical device software – Software life-cycle processes
IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Additional Information

Certificates Issued:

EN ISO 13485:2016 Certificate Number: SX 1135905-2
Expiry Date: 16-May-2022
MDSAP Certificate Number: MD 3347792-310
Expiry Date: 16-May-2022
EC Certificate Number: HD 60145508 0001
Expiry Date: 26-May-2024

Printed Name: Matan Neeman

Function: Q&R Director

Signature: _____

Date of Issue: 15-Jul-2021

End of Document

Record ID: DHF373417 Rev LF
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