PHILIPS

CE 0123

DECLARATION OF CONFORMITY

We, Philips Medical Systems DMC GmbH, declare under our sole responsibility that the product:

Product Name:	**MobileDiagnost wDR**
Product Model Number or Designator:	**Mar 2019**
Control Indicator:	**all**
Start of CE Marking:	**2011**
Device Classification:	**Class IIb** (according to Directive 93/42/EEC, Annex IX, Rule 10)
Global Medical Device Nomenclature Code (GMDN) and Title:	**37647 Mobile basic diagnostic x-ray system, digital**
Product Options/Accessories:	**see Addendum 1**

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

- **Council Directive 93/42/EEC concerning medical devices**
- **Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.**

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II-Section 3.2 of the Medical Device Directive. Copies of the Quality System certificates are available upon request.

Name/Address of Notified Body: **TÜV Süd Product Service GmbH / Ridlerstr. 65, D-80339 München, Germany**

Authorized EU Representative:	**not applicable**
Supplementary Information:	**not applicable**

The products listed above have been designed, manufactured, tested and found to be compatible with the devices and accessories described by the manufacturer in the device accompanying documentation.

Philips Medical Systems DMC GmbH, as the Responsible Manufacturer for the MobileDiagnost wDR mobile X-ray system, in accordance with the EU Medical Device Directive 93/42/EEC (CE), declares that the product MobileDiagnost wDR is produced exclusively for Philips Medical Systems DMC GmbH by the Sub-contractor:

Sub-contractor's Name : SEDECAL SA

Sub-contractor's Address: Palaya, 9-13, Pol. Ind Rio de Janeiro, 28110 Algete, Madrid, Spain

Both SEDECAL and Philips Medical Systems DMC GmbH are certified to ISO13485 and EU Medical Device Directive 93/42/EEC.

Philips Medical Systems DMC GmbH Hamburg Germany

Signature (signed for and on behalf of Philips)

Printed Name: **Michael Mizrachi**
Title: Head of Q&R, Diagnostic X-ray, Hamburg

Hamburg, 22.03.2019

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ADDENDUM I
DECLARATION OF CONFORMITY
Belonging to DXR-QR-0095-12

List of Product Options/ Accessories

- Grid Landscape for SkyPlate large
- Grid Portrait for SkyPlate large
- Grid Portrait for SkyPlate small
- Grid for SkyPlate E
- Handle for SkyPlate large
- SkyPlate Cable
- Dose Area Product Meter
- Portable Panel Protector
- Mobile Detector Holder
- Detector Holder Patient Bed
- WPD Hygenic Bag – Large
- WPD Hygenic Bag – Small
- SkyPlate Charger 2EZ
- Battery for SkyPlate
- SkyPlate Detector large
- SkyPlate Detector small
- SkyPlate E Detector
- SkyFlow
- SkyFlow Plus
- Wireless remote control
- long sliding Column
- 20/40kW Generator

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ADDENDUM II
DECLARATION OF CONFORMITY
Belonging to DXR-QR-0095-12

The products and their options listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the standards listed below. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation:

Product Safety Standards – General Standard:

EN 60601-1:2006/A1:2013 (Ed. 3.1)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Product Safety Standards – Particular Standards:

EN 60601-2-28:2010	Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
EN 60601-2-54:2009	Medical electrical equipment – Part 2-54: particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Product Safety Standards - Collateral Standards

EN 60601-1-2:2015	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
EN 60601-1-3:2008/A1:2013 (Ed.2)	Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
EN 60601-1-6:2010	Medical Electrical Equipment – Part 1-6: Usability

Other relevant Standards

EN 62304:2006	Medical Device software – software life cycle processes
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices
EN 62366:2008	Medical devices – Application of usability engineering to medical devices