Declaration of Conformity

Medtronic

Notified body	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg, Germany
Manufacturer	Medtronic Navigation, Inc. (Littleton) 300 Foster Street Littleton, Massachusetts 01460 USA
Authorized representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Tel: 31 45 566 80 00

Description of the product

Product Name and Number

Label Part Number	Material Description
BI-700-02000*	BASE SYS BI70002000 O-ARM SYS O2
BI-700-02000R	BASE RFB BI70002000 O-ARM SYS O2
BI-750-00029	CONFIG BI75000029 O2 HI DEF 3D HD3D
BI-750-00033	CONFIG BI75000033 O2 ENHAN CRAN 3D EC3D
BI-750-00030	CONFIG BI75000030 O2 ADVANCED VIEWING
BI-750-00031	CONFIG BI75000031 O2 ISO-WAG ROTATION
BI-750-00032	CONFIG BI75000032 O2 COLLIMATED AXIAL 3D
BI-750-00034	CONFIG BI75000034 O2 MULTI FIELD OF VIEW
BI-750-00035	CONFIG BI75000035 O2 STEREOTAXY
BI-400-00015	SPACER BI40000015 O-ARM PATIENT SPACER
BI-750-00024	KIT BI75000024 MVS PRINTER OPTION
BI-750-00028	CONFIG BI75000028 O2 REMOTE PENDANT
BI-750-00027	CONFIG BI75000027 O2 SYS NAV INTERACE
BI-710-00170	KIT SVC BI71000170 COMPUTER O2 IAS
BI-710-00169	KIT SVC BI71000169 COMPUTER O2 MVS SERVR
BI-710-00518	KIT SVC O2 BI71000518 O-ARM SW 4.0.1 OUS
BI-710-00520	KIT SVC O2 BI71000520 COMP MVS SER 4.0.1
BI-710-00172	KIT SVC O2 BI71000172 DETECTOR PANEL ARRAY 4030D
BI-710-00168	KIT SVC O2 BI71000168 COLLIMATOR W DYN FILTER
BI-400-00015	SPACER BI40000015 O-ARM PATIENT SPACER
BI-710-00196	KIT SVC O2 BI71000196 TUBE X-RAY A132
BI-710-00071	UPGD KIT BI71000071 12:1 GRID
BI-710-00518	KIT SVC O2 BI71000518 O-ARM SW 4.0.1 OUS
BI-710-00517	KIT SVC O2 BI71000517 O-ARM SW 4.0.1 USA
BI-710-00521	KIT SVC O2 BI71000521 COMP IAS SER 4.0.1
BI-710-00520	KIT SVC O2 BI71000520 COMP MVS SER 4.0.1
BI-710-00546	BI71000546 O-ARM SW 4.0.2 OUS
BI-710-00545	BI71000545 O-ARM SW 4.0.2 USA
BI-710-00548	KIT SVC O2 BI71000548 COMP IAS SER 4.0.2
BI-710-00547	KIT SVC O2 BI71000547 COMP MVS SER 4.0.2
BI-900-00048	MOUSE BI90000048 OARM WIRELESS 10PK
9732722	DRAPE 9732722 TUBE STERILE O-ARM 20PK
9733023	DRAPE 9733023 BAR STERILE O-ARM 20PK

* These systems are composed of one Image Acquisition System Model No. BI-700-00273 and one of the following:

Mobile View Station Model No. BI-700-00313	100 volt, type B power plug
Mobile View Station Model No. BI-700-00314	120 volt, type B power plug
Mobile View Station Model No. BI-700-00315	240 volt, type I power plug
Mobile View Station Model No. BI-700-00316	240 volt, type F power plug
Mobile View Station Model No. BI-700-00325	240 volt, type G power plug
Mobile View Station Model No. BI-700-00326	240 volt, type H power plug
Mobile View Station Model No. BI-700-00327	240 volt, type J power plug
Mobile View Station Model No. BI-700-00328	240 volt, type K power plug
Mobile View Station Model No. BI-700-00330	240 volt, type M power plug
Mobile View Station Model No. BI-700-00331	240 volt, type N power plug

Indications for Use:	The O-arm® O2 Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. The O-arm® O2 Imaging System is compatible with certain Image Guided Surgery Systems.
Medical Device Directive Classification	O-arm O2 Imaging System and Options: Class IIB-Annex IX, Rule 10 Sterile Accessories (Drapes and 1D Mouse): Class 1(Sterile)-Annex IX, Rule 1

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Provisions to which the product conforms	**Medical Device Directive 93/42/EEC**
Conformity Assessment Route	**For O-arm O2 System: Annex II, Full Quality Assurance System, For Sterile Accessories: Annex V, Production Quality Assurance**

Harmonized standards (applied in full or part)

EN ISO 13485:2012/AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971:2012 Medical devices-Application of risk management to medical devices.

EN 980:2008 Symbols for use in the labeling of medical devices.

EN 1041:2008 Information supplied by the manufacturer of medical devices.

EN ISO 11137-1:2015 Sterilization of health care products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

EN ISO 11135-1:2007 Sterilization of health care products-Ethylene oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

EN ISO 10993-7:2008 Biological Evaluation of medical devices, Part 7 Ethylene oxide sterilization residues

EN 556-1:2001/AC:2006 Sterilization of Medical Devices-Requirements for Medical Devices to Be Designated "Sterile"-Part 1: Requirements for Terminally Sterilized Medical Devices

EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

EN 60825-1:2007 Safety and laser product Equipment Classification and Requirements

EN 60601-1-6:2010 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral standard: Usability.

EN 62366:2008 Medical Devices – Application of usability engineering to medical devices

EN 62304:2006/AC:2008 Medical device software - Software life-cycle processes IEC 62304:2006

EN 60601-1:2006 /AC:2010/AC 2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2007/AC:2010 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

EN 60601-1-3:2008/AC:2010 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X- ray equipment

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

EN 60601-2-43:2010 Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures

Particular conditions applicable to the use of the product	Users should be trained, licensed, and/or certified in the proper use of medical x-ray equipment and its medical applications.	
Notified body	0197 (TÜV Rheinland LGA Products GmbH	
Certificate number and effective dates	HD 60113441 0001 Design and development of x-ray Equipment Nov 19, 2011 – Nov 18, 2021	DD 60113440 0001 Aspects of manufacture concerned with securing and maintaining sterile conditions for sterile drapes and image selector mice Nov 19, 2016 – Nov 18, 2021
Period of validity of this declaration of conformity	This declaration applies to O-arm O2 Imaging Systems with serial numbers 977, 1053, 1188, 1249, 1255, 1264, 1266, 1269, 1278, 1284, 1286, 1288 through 1293, 1296 through 1300, 1302, and 1304 and above as well as all O-arm O2 Imaging Systems with "R" suffix serial numbers.	

This Declaration of Conformity is issued under the sole responsibility of the manufacturer and covers all medical devices as specified in the packing list and/or labels belonging to this declaration and is only valid in connection with the unit or component specific documentation accompanying the unit certification.

Name and position of signatory	Paul Smolenski, Sr. Manager, RA
Signature, date and place	Paul Smolenski at Littleton, Massachusetts 01640, USA 13-Apr-2017