PerkinElmer®
For the Better

DECLARATION OF CONFORMITY
KONFORMITÄTSERKLÄRUNG

We
Wir

PerkinElmer Technologies GmbH & Co. KG, In der Rehbach 22, DE-65396 Walluf

declare under our sole responsibility, that the product:
erklären in alleiniger Verantwortung, dass das Produkt

XRpad™ Digital X-Ray Detector System

Model
Typ
XRpad 4336 MED

Material Nr.
Materialnummer
95510925

to which this declaration relates is in conformity with the following standards
auf das sich diese Erklärung bezieht, mit den folgenden Normen übereinstimmt

EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN IEC 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ETSI EN 301 893 V1.7.1	Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN
ETSI EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
ETSI EN 301 489-17 Ver. 2.2.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 4090:2004	Photography - Medical radiographic cassettes/screens/films and hard-copy imaging films - Dimensions and specifications
EN IEC 62220-1:2004	Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency
EN IEC 60529:1991 + A1:2000	Degrees of protection provided by enclosures (IP code)
EN IEC 62366:2008	Medical devices - Application of usability engineering to medical devices
EN ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

following the provisions of directive/s
gemäss den Bestimmungen der Richtlinie/n

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD)

Medical Device Class according to Annex IX of the COUNCIL DIRECTIVE 93/42/EEC
Medizinprodukte Klasse gemäß Anhang IX der Richtlinie 93/42/EWG des Rates über Medizinprodukte

Class IIa
Klasse IIa

Notified Body *Benannte Stelle*	CE 0050	The National Standards Authority of Ireland 1 Swift Square, Northwood, Santry, Dublin 9, Ireland
Classification GMDN *Klassifizierung GMDN*		60265 - X-ray system digital converter
Conformity Assessment According to *Konformitätsbewertung gemäss*		Annex II of the COUNCIL DIRECTIVE 93/42/EEC *Anhang II der Richtlinie 93/42/EWG des Rates über Medizinprodukte*
Year of CE marking *Jahr der CE-Kennzeichnung*		2014

PerkinElmer Technologies GmbH & Co. KG, DE-65396 Walluf, 2014-04-11

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