By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 551576**

Issued To: **Philips India Limited**
Plot No. B-79, MIDC, Phase-II, Chakan
Taluka - Khed, Village - Savardari
District: Pune
Maharashtra
410 501
India

In respect of:

The design, development and manufacture of X-ray imaging systems for medical diagnostic and interventional procedures and Respiratory monitoring systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **18 December 2009** Date: **04 July 2016** Expiry Date: **17 December 2019**

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Supplementary Information to CE 551576

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Product	**Classification**
Allura FC	Class IIb
Allura Centron	Class IIb
BV Vectra	Class IIb
PrimaryDiagnost PrimaryDiagnost AR PrimaryDiagnost DR	Class IIb
MobileDiagnost Opta	Class IIb
Intuis	Class IIb
Children's Respiration Monitor	Class IIa

First Issued: **18 December 2009** Date: **04 July 2016** Expiry Date: **17 December 2019**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	**Service(s) supplied**
Philips Digital Mammography Sweden AB Smidesvägen 5, 171 41, SOLNA, Sweden	**Design** **Manufacture**
Philips Healthcare (Suzhou) Co Ltd No. 258, Zhong Yuan Road Suzhou Industrial Park 215024, Suzhou, Jiangsu Province China	**Manufacture**
Philips India Limited 1st Floor,Devi ICC Gaurav Tech Park Old Mumbai-Pune Highway, Pimpri Pune, Maharashtra 411 018 India	**Design**

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Subcontractor:	**Service(s) supplied**
Philips Medical Systems Netherland B.V. Veenpluis 4-6 5684 PC Best, Netherlands	**EU Representative**
Saakshi Machines & Tools Pvt Ltd. El-23,J Block, M.I.D.C., Bhosari,Pune 411026 India	**Crucial Supplier**
SFO Technologies Pvt Ltd. Plot No.37, CSEZ, Kakkanad, Cochin Kerala 682 037 India	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Technix SpA via Enrico Fermi 45 Grassobbio (BG) 24050 Italy	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
18 December 2009	7388739	First Issue.
17 June 2010	7535359	Re-issue due to name change from Alpha X-Ray Technologies (i) Pvt Ltd to Philips Electronics India Ltd. Minor change to company street address from Plot No 102, Jawahar Co-Op Industrial Estate to Plot No.102 Jawahar Ind Estate Ltd
06 June 2012	7755746	Re-issue due to change of scope, merging with CE 559965, relocation of the company from Navi Mumbai to Pimpri, Pune, Maharashtra, India and addition of manufacturing site; Mahalunge, Pune, Maharashtra, India
13 December 2012	7903566	Removal of products 'Meditronics Mobile Drive' and 'Meditronics Floatex' from the supplementary page. Change of address for subcontractor 'Philips Electronics India Ltd.' from village Mahalunge to village Savardari. Correction of address for EU Representative from 'Veenpluis 4' to 'Veenpluis 4-6'.
19 February 2013	7948596	Addition of "Allura Centron" to Supplemetary page.
09 January 2014	8091462	Re-issue due to Name change from 'Philips Electronics India Ltd' to ' Philips India Limited' Legal Manufacturer site change and addition of 'Philips Healthcare (Suzhou) Co., Ltd.' under the list of significant sub-contractor for 'manufacture' activities.

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Date	Reference Number	Action
10 December 2014	8247062	Re-issue following 5 year renewal. Addition of products BV Vectra, Primary Diagnost AR and Primary Diagnost DR in supplementary page. Addition of TECHNIX SPA and Philips Digital Mammography Sweden AB under the list of significant subcontractors. Addition of Crucial Suppliers as per Unannounced Audit visit requirements.
13 October 2015	8424733	Addition of "Product Intuis" to Supplemetary page.
04 July 2016	8560203	Scope extension to include Respiratory monitoring systems. Addition of product "Children's Respiration Monitor" to supplementary page.