EC CERTIFICATE

Full Quality Assurance System

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

No. 5-768-200-1411

The **Directorate of Device Testing and Clinical Engineering (EMKI)**

certifies that the manufacturer:

MEDIMA Sp. z o. o.
Al. Jerozolimskie 200
02-486 Warsaw
Poland

for the products / product categories:

Syringe infusion pumps
Volumetric infusion pumps
Docking stations for infusion pumps
Infusion sets
Medical software

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-131-2007**

This certificate is valid until **2019-11-19** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 3 First issued: 2014-11-20

Budapest, 2018-02-26

Head of EMKI

EMKI 1840

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering
H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33
E-mail: cert@emki.hu, Web: www.emki.hu
H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate 5-768-200-1411

The certificate is valid for the following manufacturing site:

MEDIMA Sp. z o. o.
Al. Jerozolimskie 200
02-486 Warsaw
Poland

The certificate is valid for the following models:

Syringe infusion pumps:
S100, S200, S300, S300 PCA

Volumetric infusion pumps:
P, P1, P2, P100, P200, P300

Docking stations for infusion pumps:
DS302, DS304, DS306, DS308

Infusion sets:
Medima Line S
Medima Line L
Medima Line B
Medima Line

Medical software:
Medima User ToolBox
Medima Service ToolBox
MedimaNet

The detailed description of the products is kept by EMKI under No. 42-131-2007.

Issue: 3 Date: 2018-02-26 First issued: 2014-11-20

Head of EMKI

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet
Eszközminősítő és Kórháztechnikai Igazgatóság

EMKI

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