

**EC CERTIFICATE**  
**Full Quality Assurance System**

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

**No. 5-871-200-1911**

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**

**medima**

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 **2024-05-26** 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.

Budapest, 2019-11-20



Head of EMKI



EMKI 2263

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

Eszközminősítő és Kórháztechnikai Igazgatóság  
Directorate of Device Testing and Clinical Engineering

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**EMKI**

# ATTACHMENT TO EC CERTIFICATE

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## Additional information for Certificate 5-871-200-1911

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

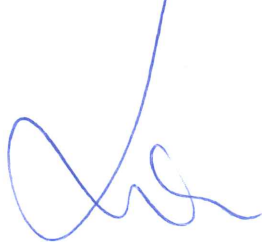
Medical software:  
Medima User ToolBox  
Medima Service ToolBox  
MedimaNet

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

Issue: 1

Date: 2019-11-20

First issued: 2019-11-20



Head of EMKI



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