



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 20 0234 QS/NB

The quality system of manufacturer

AKAS MEDICAL EQUIPMENT

**No 240/1, PERIYA COLONY, ATHIPET, AMBATTUR, CHENNAI –
600058, TAMILNADU, INDIA**

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):


Infusion pumps, syringe pumps

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2021-05-04
Valid until: 2024-05-27
First Issued: 2020-05-19
Revision: a



Date: 2021-05-04


Mgr. Jiří Heš
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 20 0234 QS/NB

issued for manufacturer:

AKAS MEDICAL EQUIPMENT
No 240/1, PERIYA COLONY, ATHIPET, AMBATTUR, CHENNAI –
600058, TAMILNADU, INDIA

Product(s):

Name: **Infusion pumps**

Trade name(s): AKAS INFUMAX, AKAS INFUMAX 5005

Model(s): AKAS INFUMAX, AKAS INFUMAX 5005

Class: IIb

GMDN: 13215

Name: **Syringe pumps**

Trade name(s): AKAS TERUMAX Rx, AKAS SYRU 4004, AKAS SYRU 6006

Model(s): AKAS TERUMAX Rx, AKAS SYRU 4004, AKAS SYRU 6006

Class: IIb

GMDN: 13217



Date: 2021-05-04
Revision: a

Mgr. Jiří Heš
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 20 0234 QS/NB
issued for manufacturer:

AKAS MEDICAL EQUIPMENT
No 240/1, PERIYA COLONY, ATHIPET, AMBATTUR, CHENNAI –
600058, TAMILNADU, INDIA

Facility(ies):

AKAS MEDICAL EQUIPMENT – Office

No 240/1, PERIYA COLONY, ATHIPET, AMBATTUR, CHENNAI – 600058,
TAMILNADU, INDIA

AKAS MEDICAL EQUIPMENT – Works


NO.26, PALAYAM BAZAAR ROAD, WORAIYUR, TIRUCHIRAPPALLI 620003.
TAMILNADU, INDIA

Certificate History:

Revision	Date	Reference Number	Action
	2020-05-19	803602799	Certification
a	2021-05-04	803602891	Models' addition (AKAS INFUMAX 5005, AKAS SYRU 4004 and AKAS SYRU 6006)



Date: 2021-05-04
Revision: a


Mgr. Jiří Heš
Representative of the Notified Body No. 1023