



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. 17 0307 QS/NB

The quality system of manufacturer

POCARD Ltd.

**3rd Cherepkovskaya 15a, building 2, office 33, Moscow 121552,
Russia**

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):

Apheresis system column, immunoadsorption, reusable

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: 2020-07-15
Valid until: 2022-06-29
First Issued: 2017-06-30
Revision: b



Date: 2020-07-15


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



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Annex to EC Certificate No. 17 0307 QS/NB

issued for manufacturer:

POCARD Ltd.

**3rd Cherepkovskaya 15a, building 2, office 33, Moscow 121552,
Russia**

Product(s):

Name: **ABO Adsopak[®]**
Trade name(s): -
Model(s): ABO Adsopak[®] - A
ABO Adsopak[®] - B
ABO Adsopak[®] - AB
ABO Adsopak[®] - A150
ABO Adsopak[®] - A300
ABO Adsopak[®] - B150
ABO Adsopak[®] - B300
ABO Adsopak[®] - AB300
Class: IIb
GMDN: 60912


Facility(ies):

POCARD Ltd.
3rd Cherepkovskaya 15a, building 2, office 33, Moscow 121552, Russia

NEARMEDIC PLUS
Gamaleya str., 18, building 4, 123098 Moscow, Russia

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Certificate History:

Revision	Date	Reference Number	Action
-	2017-06-30	803602534	Certification
a	2019-08-29	833600143	Manufacturer address change
b	2020-07-15	803602828b	Adding the models of the adsorption columns with plastic housing and increased column volumes from 100 ml to 150 ml and from 200 ml to 300 ml.



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