Joint-Stock Company POLISORB
Legal address (Factual address): 456652, Russia, Chelyabinsk region,
Kopeysk, Tomskaya street 14
Phone: +7 351 278 19 89, Fax: +7 351 778 51 26
E-mail: info@polisorb.com www.polisorb.com

POLISORB®

From 28.09.2023

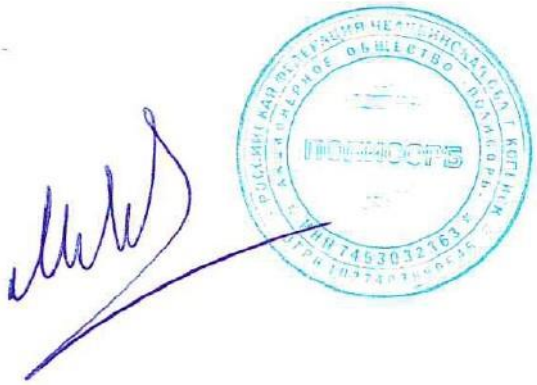
Dear colleagues,

On behalf of Polisorb JSC, I confirm the statement regarding the prolongation of our certification validity under Directive 93/42/EEC, as it is stated in Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions, till December 31, 2027.

Yours faithfully,

Mikhail Popilov

Director General of Polisorb JSC



EC Certificate – Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

Certificate No. MDD-196

Issued to:	Polisorb JSC Tomskaya Street 14, Chelyabinsk Region, Kopeysk, 456652, Russian Federation
Place of production:	Polisorb JSC Tomskaya Street 14, Chelyabinsk Region, Kopeysk, 456652, Russian Federation
Place of production:	Polisorb JSC Tomskaya Street 2, Chelyabinsk Region, Kopeysk, 456652, Russian Federation
Product category:	Polisorb Intestinal mucosa barrier devices
GMDN:	58028

SIQ has audited the quality system in accordance with MDD Annex V and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on

Audit report No.:
OSV 00280/2021, 2021-05-10
OSV 00516A/2021, 2021-05-18
OSV 00670/2021, 2021-05-25
OSV 00673/2021, 2021-05-25

See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4) and continues to meet the above requirements.

Certification date: 2021-05-25

Issue: 1/2021-05-25

Valid until: 2024-05-26

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Managing Director of SIQ

Gregor Schoss

SIQ Ljubljana, Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia, Notified Body No. 1304
tel.: +386 1 4778 100 • fax: +386 1 4778 444 • e-mail: info@siq.si • http://www.siq.si

2024-05-24

Mr. Mikhail Popilov
Polisorb JSC
Tomskaya str. 14
456652 Kopeysk,
Russian Federation

Notified Body Confirmation Letter

Reference: 6686-2024/01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices.

This letter confirms that, SIQ Ljubljana, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1304 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name	Polisorb JSC
Legal address/street	Tomskaya str. 14
Zip code/town	456652 Kopeysk
Country:	Russian Federation
SRN number	TBD

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member

State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.
The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

– 26 May 2026 for Class III custom-made implantable devices;

– 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors);

– 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function;

– 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments).

On behalf of the Notified Body,

Ana Pribaković Borštnik

Product manager MDR

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

DEVICE NAME OR BASIC UDI-DI (under MDR application)	MDR DEVICE CLASSIFICATION (as proposed by the manufacturer and verified at the pre-application stage)	IF THE MDR DEVICE IS A SUBSTITUTE DEVICE, IDENTIFICATION OF THE CORRESPONDING MDD DEVICE	MDD CERTIFICATE REFERENCE(S) OF THE DEVICES UNDER MDR APPLICATION, AND THE NB IDENTIFICATION
Polisorb, Basic UDI-DI: 4606257-ENTEROSORB-MD-9J	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate MDD-196; NB#1304

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive

DEVICE NAME OR BASIC UDI-DI (under MDR application)	MDR DEVICE CLASSIFICATION (as proposed by the manufacturer and verified at the pre-application stage)	IF THE MDR DEVICE IS A SUBSTITUTE DEVICE, IDENTIFICATION OF THE CORRESPONDING MDD DEVICE	MDD CERTIFICATE REFERENCE(S) OF THE DEVICES UNDER MDR APPLICATION, AND THE NB IDENTIFICATION
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

DATE	NB INTERNAL REFERENCE TRACEABLE TO EACH VERSION OF THE LETTER	ACTION
2024/05/24	6686-2024/ 01	Initial issue