

«TahatAksi» ALC

Legal Address: Selitskogo str., 7, Bld. 4, Office 101

220075, Minsk, Republic of Belarus

Office address: Rokossovskogo ave., 166, Premises 1N

220101, Minsk, Republic of Belarus

Phone / Fax: + 375 17 375 58 42, + 375 17 375 58 46

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reliability and trust!

Manufacturer's Declaration

Date: May 8, 2024

Re: Declaration of the status of transmission of MDR, including a formal application, written agreement, and appropriate Manufacturer following works according to the surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices

To: Whom that may concern

WHEREAS

We, **TAHATAKSI ALC**, who are official manufacturers of blood and infusion solutions warming devices, patient warming systems, newborn warming systems, having factories at **166, Rokossovskogo Ave., Premises 1N, 220101, Minsk, Republic of Belarus**, hereby declare that

We have submitted 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 INSTITUTE FOR TESTING AND CERTIFICATION, INC., a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 1023 on NANDO .

We have been processing the MDR transmit and conduct all the works according to the standards of MD and it is estimated we will transmit into MDR by the fourth quarter of 2028. The exact date is subject to the actual date we get the MDR approval.

Minsk, May 8, 2024



Siarhei Shmyk
Director

