JMS SINGAPORE PTE LTD

440 Ang Mo Kio Industrial Park 1

Singapore 569620, SINGAPORE

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
Ms. Chia Chin Yin	Ms. Suticha Suwansath	+66 2 564 8041 Ext. 326/ suticha.s@tuvsud.com	-	2024-05-22	1 of 3

TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: TPS2344/TH0270023T119

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: SG-MF-000024704

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.

To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-22

TÜV SÜD Product Service GmbH
Medical and Health Services

Ms. Suticha Suwansath
Conformity Assessment Responsible (CARE)

Signed by / Podpisano przez:
JAROSŁAW GAUDYN
Date / Data: 2024-06-17 15:26

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Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
Device 1: Transfer Bag/ BUDI DI: 8888483JMSTBGN
Device 2: Pooled Platelets Storage System/ BUDI DI: 8888483JMSPPSST7
Device 3: A.V.Fistula Needle Set/ BUDI DI: 8888483JMSAVFHE
Device 4: Extension Tube/ BUDI DI: 8888483JMSETGD
Device 5: Infusion Set/ BUDI DI: 8888483JMSINFC2BBS
Device 6: Infusion Set/ BUDI DI: 8888483JMSINFHW
Device 7: IV Cannula/ BUDI DI: 8888483JMSIVCIVAJ2
Device 8: IV Cannula/ BUDI DI: 8888483JMSIVCJG
Device 9: Scalp Vein Set/ BUDI DI: 8888483JMSSVSM2
Device 10: Transfusion Set/ BUDI DI: 8888483JMSTRFBNNLR
Device 11: Transfusion Set/ BUDI DI: 8888483JMSTRFBVNMH
Device 12: Transfusion Set/ BUDI DI: 8888483JMSTRFKZ
Device 13: Transfusion Set/ BUDI DI: 8888483JMSTRFNN5W
Device 14: Closed System Drug-Transfer Device (CSTD)/ BUDI DI: 8888483JMSCSDTDXT
Device 15: Infusion Set/ BUDI DI: 8888483JMSINFC1BBP
Device 16: Infusion Set/ BUDI DI: 8888483JMSINFC1WD
Device 17: Blood Bag/ BUDI DI: 8888483JMSBBEY
Device 18: Blood Bag with In-Line Leukocyte Filter for Red Cells / BUDI DI: 8888483JMSBBRCFUG
Device 19: Blood Bag with In-Line Leukocyte Filter for Whole Blood / BUDI DI: 8888483JMSBBWBFV6
Device 20: Cord Blood Bag/ BUDI DI: 8888483JMSCBBFL

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Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-22	TPS2344/TH0270023T119	Initial issue