Date of issuance: 22 May 2026

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC PP 001/2026

The following lot of TISSEEL, [Fibrin Sealant] Frozen Solution (MAL15045084AZ) produced by Takeda Manufacturing Austria AG, AUSTRIA, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

- [√] National requirement on Good Distribution Practice for Cold Chain
- [ ] National requirement on Lot Summary Protocol Evaluation
- [ ] National requirement on Physical Appearance Testing
- [ ] Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives, WHO Technical Report Series, No.840, 1994, Annex 2

Product Registration Holder:	BAXTER HEALTHCARE (MALAYSIA) SDN. BHD.
Lot no:	D8C010AB
Expiry date:	31 December 2026
No. of doses:	357
No. of doses per container:	1

Signature:

Name of authorized person: **DR. AZUANA BINTI RAMLI**
Deputy Director General of Health (Pharmaceutical Services)
Ministry of Health Malaysia