



bloom

Quality Letter

1. Storage and Transport Conditions

Distributing partner shall ensure that a device's storage or transport conditions comply with conditions set by Bloom and documented on the product label and in IFU. Detailed information is stated in [Annex 1](#).

2. Complaints

Contact information:

- Email: support@bloomdiagnostics.com
- Fax: 0041 434302378
- Phone number: +43 (0)1 9297296

Distributing partner shall immediately forward to Bloom any received complaints from users about suspected incidents related to a device.

Where Distributing partner considers or has reason to believe that the device is not in conformity with the Regulation or presents a serious risk, it shall without any delay inform Bloom, in order to ensure the correct incident reporting (if required), providing all available details of the non-compliance/incident.

3. Repackaging and Relabelling

The packaging provided by Bloom complies with the local regulatory requirements and the Distributing partner shall not interfere or change the packaging. If an adaptation of the packaging is needed Distributing partner shall request Bloom to carry out the required label change.

4. Marketing and Product Information

Distributing partner agrees to conduct no changes to the provided material without Bloom's approval. If Distributing partner wants to place marketing/product information on the market (e.g. via website, webshop, social media channels, events, advertising or print) the materials/information must be approved by Bloom prior to its placement. If a Distributing partner needs a translation for any Bloom product material, the Distributing partner can either request this translation directly from Bloom, or shall send the final locally translated file to Bloom for approval. If the Distributing partner is translating the files locally, Bloom's Glossary must be provided to the partner and followed by him.

5. Amendments to Quality Letter

Bloom will notify the Distributing partner about major amendments to this Quality Letter. The latest version of Quality Letter can be found on Bloom's website <https://bloomdiagnostics.com/en/library>.

Distributing partner: *Name / Function*

Signature:

Date:

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Annex 1. Temperature and Humidity Exposure Limits Bloom Products

Product	REF number	Long Term Temperature Exposure Limits		Short Term Temperature Exposure Limits		Humidity Exposure Limits	
		Temperature range	Shelf life	Peak Temperature range	Duration	Peak Humidity	Duration
FER	FER-REF-1-2.0, FER-REF-3-2.0	2°C to 30°C	18 months	-20°C to 50°C	Max. 5 days	up to 80%	End of shelf life
	FER-REF-1-2.1, FER-REF-3-2.1						
AMH	AMH-REF-1-2.1, AMH-REF-3-2.1	2°C to 8°C	11 months	-20°C to 45°C	Max. 3 days	up to 80%	End of shelf life
	AMH-REF-1-2.2, AMH-REF-3-2.2						
TSH	TSH-REF-1-1.0, TSH-REF-3-1.0	2°C to 30°C	18 months	-20°C to 50°C	Max. 5 days at 50°C and 2 days at -20°C	up to 80%	End of shelf life
	TSH-REF-1-1.1, TSH-REF-3-1.1						
CYC	CYC-REF-3-1.0	2°C to 30°C	18 months	-20°C to 50°C	Max. 2 days	up to 80%	End of shelf life
CRP	CRP-REF-3-1.0	2°C to 30°C	12 months	-20°C to 50°C	Max. 2 days	up to 80%	End of shelf life