

Yumizen G CLEANER

- Yumizen G800
- Yumizen G1500/G1550

REF 1300036420

CLEANER 1 x 4.5 L

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

Washing solution.

Intended Use ^{a b}

Yumizen G CLEANER is a washing solution used for daily maintenance and cleaning of Yumizen G Line fully automated coagulation analyzers during routine use. For *in vitro* diagnostic use only.

Reagents ^c

Yumizen G CLEANER is ready-to-use. It is a surfactant used for daily maintenance and cleaning of the coagulation analyzer.

Stabilizer < 0.5%

Yumizen G CLEANER should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling ^d

1. Allow the tank to stand for at least 30 min (room temperature).
2. Refer to the maintenance chapter of the instrument user manual to install the new tank.

Materials Required but not Provided ^e

- Hemostasis analyzer

- HORIBA Medical analyzers (Yumizen G Line) are recommended.
- Standard laboratory equipment

Storage and Stability

Stability before opening

Stable up to the expiry date on the label if stored at 15 - 35°C.

Stability after opening

	15 - 35°C
Yumizen G CLEANER	60 days

Waste Management ^f

Please refer to local legal requirements.

General Precautions ^g

- This product is for professional *in vitro* diagnostic use only.
For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- Do not pipette by mouth.

^aModification: § "Intended Use" changed.

^bModification: new leaflet form.

^cModification: § "Reagents" changed.

^dModification: § "Handling" changed.

^eModification: § "Material Required but not Provided" changed.

^fModification: chapter added.

^gModification: § "General Precautions" changed.

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- Do not replenish the products.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The product vials should be discarded after use. Disposal of all waste material should be in accordance with local guidelines.
- Please refer to the SDS associated with the product.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA Medical representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the product used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.
- Using of third-party hemostasis analyzers may cause a risk of system un-harmonization.
- It is the user's responsibility to evaluate the risk of using a third-party hemostasis analyzers.