

List of CDS Related Guidance

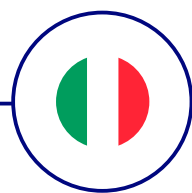
Processing Requirements for Thermolabile Flexible Endoscopes



CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes

Italy



Procedure Room	Decontamination Area				
Precleaning	Manual Cleaning*	Manual Disinfection or EWD	Drying/Storage/ Sterilization	Remarks	Source
Immediately after finishing patient's procedure		Manually or EWD processing Mainly PAA -based disinfectants Spectrum of antimicrobial activity: bactericidal (incl. mycobactericidal), fungicidal, virucidal, and sporicidal	EtO sterilization is uncommon; instead, alternative methods such as LTSF and H₂O₂ (ASP Sterrad, Steelco PL 130, and Steris V-Pro series) Trend towards LCS in EWD	BF: trend towards sterilization TJF: trend towards sterilization, at least for immune-compromised patients URF and CYF (CHF if used percutaneously): need to be sterile if used in the OR	Italian guideline issued by the National Association of Endoscopy Technical Operators is based on ESGE/ESGENA guidelines (last update 2011 , currently under review) Technical Report UNI/TR 11662 on reprocessing of medical devices – Guide for the reprocessing of thermolabile endoscopes (2016) https://www.gimprios.it/r.php?v=3325&a=32951&l=339883&f=allegati/03325_2019_04/fulltext/156-157_Rivara.pdf http://store.uni.com/catalogo/uni-tr-11662-2016?josso_back_to=http://store.uni.com/josso-security-check.php&josso_cmd=login_optional&josso_partnerapp_host=store.uni.com
Legend: EWD – endoscope washer-disinfector (chemo-thermal mechanical/ automatic cleaning and disinfection) GDA – glutardialdehyde		PAA – peracetic acid ClO ₂ – chlorine dioxide LCS – liquid chemical sterilization EtO – ethylene oxide	LTSF – low-temperature steam formaldehyde H ₂ O ₂ – hydrogen peroxide OR – operating room EHEF – European Hygiene Experts Forum		

* Mandatory, even in the case of EWD processing

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As medical knowledge is constantly growing, technical modifications or changes of the product design, product specifications, accessories and service offerings may be required. This quick reference guide is a mere summary of some important procedure steps and/or product information. It is not meant to replace the instructions for use. Any user of this product must at all times observe all mandatory information for the product, found, in particular, on the labels and the instructions for use.



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