MDR 2017/745

and

ISO 17664-1:2021

Impact Analysis for Hospitals relating to

Repurposing of Reusable Rigid Endoscopes

A guide to resilient compliance under the
MDR and ISO 17664

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Introduction

There have been scandals in the past due to improper reuse of endoscopes. They had not been cleaned properly, causing patients to contract hepatitis. These patients had to be treated. Some never recuperated from the infection, causing human suffering and litigation against hospitals. It is essential that endoscopes are properly maintained, managed, repaired and/or replaced.

The European Medical Device Regulation 2017/745 (MDR) is a new set of regulations that governs the production, distribution, use and reuse of medical devices in Europe. Compliance with the regulation is mandatory for medical device manufacturers as well as organisations reusing and repurposing these devices in the European marketplace. The MDR 2017/745 has a life-cycle approach to medical device regulation, in which hospitals and specfically sterilisation departments play a vital role.

European Regulation 2017/745 provides an excellent and necessary reason to enhance procedures and processes towards reprocessing of reusable medical devices. "Reprocessing" refers to a process carried out on a used device in order to allow its safe reuse. It includes cleaning, desinfection, sterilisation and related procedures, including, but not limited to, testing and restoring the technical and functional safety of the used device.

Under MDR 2017/745, reusable rigid endoscopes now fall under subclass Class IIa medical devices (including Class Ir). These devices are now under a higher level of scrutiny and regulatory oversight. Extensions won't be granted and grandfathering in legacy devices will be strictly prohibited.

Since May 26, 2021, every new Class IIA device must have an MDR CE mark to be placed on the market.
This means, at least, that any new endoscope that has not undergone MDR conformity assessment or does not qualify as an MDD legacy device under an existing, valid MDD certificate is non-compliant to the new regulation and cannot be used on patients.

Current Situation

As a result of the MDR and the MDR harmonized standard EN ISO 17664-1:2021, user Manuals need to be specific about how a user can determine material degradation that may determine if a rigid endoscope is still fit to be cleaned for another re-use cycle or what the maximum number of re-use cycles is, rather than provide non-specific disclaimers, notes and warnings that may be subject to a degree of interpretation. For example, a human can never judge if a fiber package is 20-25% defective by simple observation only. In addition, a gradual decline in quality cannot be observed.

Most importantly, the Regulation states that the manufacturer must describe how a user can identify that re-use is no longer possible; limitations and restrictions that limit the service life must be provided to the user according to EN ISO 17664-1:2021.

Specifically, EN ISO 17664-1:2021 states that inspection methods and performance criteria for inspecting and testing the device must be specified by the manufacturer to ensure proper function and safe use after cleaning (clause 6.9 and Table B.1). If the manufacturer does this, the end user must comply, otherwise the device is not used within CE marked scope. Devices no longer in CE marked scope should no longer be used. Hospitals need appropriate procedures and criteria to be able to determine if re-usable devices are still in scope of the CE mark after re-use. Otherwise they cannot be certain that the device may be used on the next patient.

Alternatively, a manufacturer can specify in the IFU how many re-use cycles an endoscope can go through. If a maximum number of re-uses is not specified, clear specifications for re-use related quality parameters become even more important. As far as Dovideq is aware at the date of this document no endoscope, manufacturer has specified clear re-use related quality failure parameters. References in the instructions for use (IFU) to inspection procedures that are not suitable for adequately confirming that, for a given device, re-use is possible or not, puts hospitals at risk because they cannot empirically confirm if the device is safe to be re-used. As a result, patient safety is potentially jeopardized and claims can be directed to manufacturers, hospitals and repair facilities if patients are harmed.

Current Situation - Impact on Hospitals
The user manuals that Dovideq encounters are written based on residual risks against which warnings are provided, but are not drafted in a way to assist the end user in determining adequately if the device has not suffered degradation to the point that it should no longer be re-used. This puts the risk of additional re-use on the user, while the MDR requires a manufacturer to specify procedures for maintenance and how to identify when the device is no longer safe to reuse[1] . The manufacturer must also specify how to clean, maintain, functionally test, and sterilize the device properly. The Regulation[2] further states that the manufacturer must provide information on the appropriate processes to enable reuse and how to establish when the device is no longer safe to re-use.

Degradation or x times used
As an example of how to identify when the device should no longer be used, the regulation states that a manufacturer may describe signs of material degradation that are indicative of this. This would imply that the manufacturer describes how the end user can determine that re-use is no longer possible. If the manufacturer describes a procedure or technique for this, the manufacturer would need to have validated that technique or procedure. As an alternative example, the MDR states that the manufacturer may give a maximum number of re-use cycles after which the device should not be used anymore.
If the manufacturer specifies either or both, the end user must adhere to these or risk that the device is no longer within the CE marked scope and the end user is not allowed to use the device on patients anymore.
If the manufacturer does not specify any criteria, the result is that, currently, the manufacturer may not be compliant with MDR labeling requirements and the hospital is not able to trust that it can determine for itself if the device can be re-used safely within the CE marked scope.

Hospital Responsibility
The hospital is responsible for using CE marked medical devices on patients, which includes responsibility for correct and safe re-use of an endoscope. This implies procedures on how to determine if an endoscope is at the end of its useful life, regardless of whether the instructions for use provide clear directions for this.
Policy & Procedure
Furthermore, because the hospital is responsible for treating the patient with safe and compliant devices, the hospital must be able to rely on repurposing procedures on-site that are demonstrably robust and compliant, taking into account the specifics prescribed by manufacturers. They must ensure that testing is performed in accordance with these requirements.

Validation
The acceptance criteria for the re-use procedure should be validated as well. This allows the hospital to create documentary evidence that its re-use process reproducibly meets the specified requirements and that the process produces safe devices within CE marked scope that can be used safely on patients in accordance with hospital responsibility under applicable laws.

Lack of testing parameters
If the manufacturer does not provide information enabling identification of when the device should no longer be used (e.g. objective levels of damage, contamination or visual imparation that cause a scope to no longer be in scope of CE marked parameters), the hospital cannot be certain that re-use can be properly performed or verified and must take a risk by defining its own criteria and procedures that may turn out to be inadequate to establish that the device is still within CE marked scope, making hospitals non-compliant.

Evidence
Therefore, it is important that a hospital is able to demonstrate what it has done to determine that an endoscope can still be used and to be able to link this to criteria provided by the manufacturer to ensure that the device remains within CE marked scope after completion of procedures to prepare the device for re-use. For this purpose a simple visual check will normally not suffice because it is generally not sufficient to identify all relevant signs of material degradation. Performing an inadequate check does not prove that a device is still in CE marked scope and can be re-used safely.

During a comparative study between an automated testing device (ScopeControl) and surgeons' evaluation done at the university of Lyon, one hundred sixty-six controls were carried out with 51 different rigid endoscopes. According to the surgeon's evaluation, 78.9% and 80.7% of controls were considered as satisfactory for image and brightness quality,

1 Article 5 paragraphs 1 and 2
1: Placing on the market and putting into service
A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2: A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

2 Annex I - 23.4 sub n.
23.4. Information in the instructions for use
The instructions for use shall contain all of the following particulars: if the device is reusable, information on the appropriate processes for allowing reuse, including: cleaning, disinfection, packaging and,where appropriate, the validated method of re-sterilisation ... Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;

Results obtained using ScopeControl found that 13.3% of controls were considered as "passed," 31.3% "in danger," and 55.4% "failed," with poor correlation with the surgeons' evaluation.

The study concluded that an automated independent testing device achieved an objective and consistent quality control of endoscopes and could, in practice, better avoid the use of defective endoscopes in the surgery unit than a surgeon and thus improve the quality of the surgical procedure.

Because it is the obligation of the hospital to only use safe and compliant devices on patients, it is incumbent on the hospital to monitor quality and the decline of quality, when a device needs to be replaced or repaired and to validate a quality process based on a reproducible process based on empirical data.

Replacement
If the manufacturer does not specify a maximum number of uses nor provides specific information on when a device should no longer be used as a result of material degradation, the hospital is at risk of not being able to establish re-use procedures that lead to output of compliant devices and of not being certain when a device should no longer be re-used and thus be replaced in order to safeguard patient safety.

This exposes hospitals to potentially large risks: a hospital has a legal obligation to have a procedure in place that results in compliant devices, but is dependent on the manufacturer for crucial information to establish this. Working with an automated testing device, like Dovideq's LightControl and ScopeControl in combination with endoscopemanager.com, a hospital can significantly improve its ability to test for compliance with the manufacturer's criteria and, if none is avalable, to be able to define its own criteria in order to minimise its own risks and those of its patients. Subsequently, it allows for more precise testing and control of re-use cycles, making achieving compliance easier.

Advantages hospital:
- **Compliancy:** The hospital can prove that the manufacturer's instructions for use were followed and it can prove it is good enough for use.
- **Financial:** A hospital has the assurance that they are not spending more money on servicing endoscopes than necessary. A machine verifies that the device is fit for purpose based on set parameters.
- **Predictivity:** Dovideq is currently developing functionality that will enable hospitals to make predictions, so they could deteremine how many usage cycles are left before revision, replacement or reuse is necessary.
- **Quality:** The hospital knows and has documentation to prove that sterilization is carried out correctly and that maintenance is performed as required by regulations, norms and procedures.
- **Patient safety:** No incidents with patients, because appropriate procedures are proven to be followed.

Current Situation - External repair companies
The manufacturer will generally specify that instruments must be serviced and repaired only by persons authorized by the manufacturer and that only original parts must be used in all repair work. When devices have been repaired or serviced by unauthorized persons the manufacturer can no longer guarantee that the devices are in CE marked scope and will not provide continued warranty for the device.

Furthermore, the manufacturer is only liable for failure or deterioration of safe operation, operational safety and performance if all assembly, operation, system expansion, adjustment, modification and/or repair work have been carried out in accordance with manufacturer specifications and provided that the instrument has been used in accordance with the operating instructions (manual) at all times.

Some national trade organisations have developed schemes allowing repair companies to qualify within manufacturer criteria. However, following these procedures does not necessarily provide proof that a repair is performed in accordance with manufacturer specifications and that the device is still within CE marked scope. With ScopeControl, a repair company can prove that they have worked compliantly and that the endscope is again in conformity with manufacturer provided specifications.

Dovideq proposition
It is the hospital's obligation to monitor quality of the equipment in use, its regulatory status and, in case of re-use, have documentary proof that it has been reconditioned correctly for re-use. This is only feasible if the hospital knows the manufacturer specifications for re-use and how to determine when a device is no longer safe to be re-used. Visual inspection is generally insufficient and unreliable for endoscopes because visual inspection does not detect all relevant degradation that makes a device no longer safe for re-use and/or takes it outside the scope of CE marked performance. If the measurement parameters have been stablished by the hospital itself, there is a risk that these are not adequate for above purposes either, because they have not been established against the manufacture's criteria or any another validated benchmark. Dovideq has collected more than half a million measurements and facilitates independent benchmarking of endoscopes. 4 out of the 5 largest manufacturers use Dovideq's automated, connected measurement systems. Dovideq can therefore also facilitate data between hospitals and manufacturer.