MDR2017/745 & ISO 17664 Impact analysis for Hospitals Reuse of Endoscopes

Introduction

The EU MDR 2017/745 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 manufacturers & organisations reusing** in the EU.

Current Situation

As a result of the MDR, User Manuals need to be specific on how to:
1 : Determine if the device is fit for reuse after cleaning and testing
2 : Maximum reuse cycles

The MDR harmonized standard EN ISO 17664-1:2021 states that **inspection methods and performance criteria for testing the device must be specified by the manufacturer** to ensure proper function and safe use after cleaning .

If the manufacturer specifies either or both of the above, the hospital must comply, otherwise the device is not used within CE marked scope and shouldn't be used.

Current Situation - Impact on hospitals

User Manuals Dovideq found, don't help determine if the device is still fit for purpose. This puts the risk in the hands of the user, while the MDR obliges a manufacturer to specify procedures for maintenance and how to identify when the device is no longer safe to reuse.

Lack of testing parameters, Hospital's Responsibility & Need for Evidence

Hospitals must ensure that testing is performed in accordance with these requirements, but if the manufacturer doesn't provide adequate info on when the device should no longer be used, hospitals can't be sure of reuse or safety. That makes hospitals non-compliant.

So, hospitals need to take a risk by defining criteria and procedures and should demonstrate evidence for test results to ensure the device is still within CE marked scope. **A simple visual check will not suffice**, because it's not sufficient in finding signs of material degradation. Performing a known inadequate check doesn't prove a CE marked scope.

A comparative study between an automated testing device (ScopeControl) and surgeons' evaluation at Hospices Civils de Lyon concluded that an automated independent testing device could better avoid the use of defective endoscopes in the surgery unit than a surgeon and **improve the quality of the surgical procedures and safety.**

'80% of defects are not seen'

Conclusion

Manufacturers do not cover the MDR criteria, so hospitals can't comply either, meaning that the hospital can't establish compliant re-use procedures & can't be certain when a device should no longer be re-used to safeguard patient safety.

Automated testing devices like LightControl in combination with EndoscopeManager mitigates risks and enable hospitals to, at least, monitor and **record all testing data and provide validated evidence that its reuse process meets requirements of the CE marked scope** and that the process produces fit-for-purpose safe devices.

Hospital Advantages:

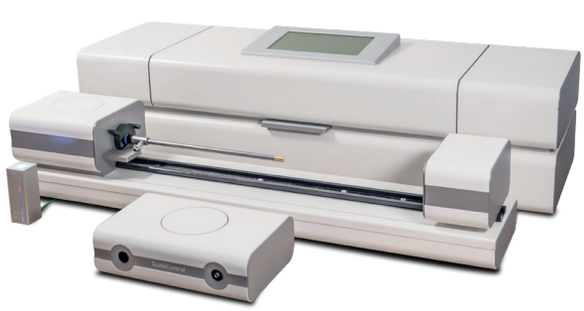
- **Compliance:** Hospitals can prove that they adhere to criteria and that the devices they use are still reusable.
- **Financial:** Lowering OR downtime saves hospitals on average €100.000,-/ year. Assurance that they do not spend more money on repairs than they need to.
- **Predictability:** Predict how many cycles a device can be used before the scope has to be serviced.
- **Quality:** Have evidence to prove that they comply with all regulations.
- **Patient Safety:** No patient incidents due to proper testing.

Dovideq Proposition

Dovideq's testing equipment is interconnected through a cloud platform that enables automated workflows, traceability and deep quality and usage analysis of endoscopes.

The platform's data also enables anonymized benchmarking between hospitals and gives clear parameters for compliance. 4/5 largest manufacturers use Dovideq systems for quality control in production, repairs and service.

With both rental and buying options, Dovideq systems are vital for quality and safety and don't break the budget.



This is a synopsis.
For the complete document, contact Dovideq

For more info visit: www.dovideqmedical.com