

SAFETY NOTICE

Subject: Potential use of stolen ophthalmic medical devices MR Q SLT s poses a risk to patients

To whom it may concern

We are formally reporting the theft of two MR Q SLT, model s, ophthalmic medical devices:

- Serial No.: 1400-015, Date of Manufacture 2024-05-09
- Serial No.: 1400-087, Date of Manufacture 2024-04-29

Please note that only the ophthalmic medical devices identified above are affected. This safety alert does not apply to other ophthalmic medical devices.

Event Details:

On 2024-07-15, it was discovered that two MR Q SLT, model s, ophthalmic medical devices had been stolen during the shipping process in Switzerland.

We appreciate your assistance in reporting any suspicious activity involving the ophthalmic medical devices listed above.

Impact:

The potential use of the identified ophthalmic medical devices poses an overall risk to users, i.e. healthcare professionals and patients.

The location of the stolen ophthalmic medical devices is unknown. Any installation, maintenance, and service of the two devices cannot be provided by the official manufacturer and its technical support.

Actions Taken:

Upon discovery of the theft, we:

- Reported the event to local law enforcement authorities
- Conducted an internal investigation

All relevant health authorities are being notified.

Relevant Immediate Actions:

If there is a suspicion or a certainty that the identified ophthalmic medical devices mentioned are being used, it is necessary to:

- Take immediate action by reporting to competent authorities for law enforcement and public health when the specified serial number is encountered
- Take immediate action by not installing the above identified ophthalmic medical device
- Take immediate action by not using the above identified ophthalmic medical device
- Take immediate action by not servicing the above identified ophthalmic medical device
- Act by reporting to the manufacturer and/or local manufacturer-authorized distributors when the specified serial number is encountered

Additional Useful Actions:

- Purchase and maintenance of medical devices only directly from the manufacturer or manufacturer-authorized distributors
- Install, maintain, and use only a medical device with identified serial number and proper labelling
- Implement additional security measures, if applicable

Request for Assistance:

Please forward this message to all healthcare professionals who need to be informed of these actions, and to any organizations to which potentially stolen ophthalmic medical devices may be distributed. If you have any information regarding this event or if you have been approached with unsolicited offers for any of the above identified ophthalmic medical devices after the date of the theft, please contact local law enforcement authorities and/or Meridian Medical.

We regret any inconvenience and appreciate your understanding that this action is taken to ensure overall user safety, i.e. healthcare professionals and patients, and customer satisfaction. If you have any further questions or require assistance regarding this safety notice, please contact Meridian Medical.

Contact Information:

For any further information or to discuss this matter in detail, please contact us directly at:

Email address: info@meridian.ch, Phone: +386 1 500 71 00, +41 33 334 11 11

Ljubljana, Slovenia, 2024-09-03

Nina Špička, CCO Meridian Medical d.o.o.

Kristijan Lamot, CO-CEO Meridian Medical d.o.o.

Davorin Gorec, CO-CEO Meridian Medical d.o.o.

Attachment:

Device data

Generic name/ kind of device: MR Q SLT s

Nomenclature id: EMDN

EMDN description: NEODYMIUM SURGICAL LASER

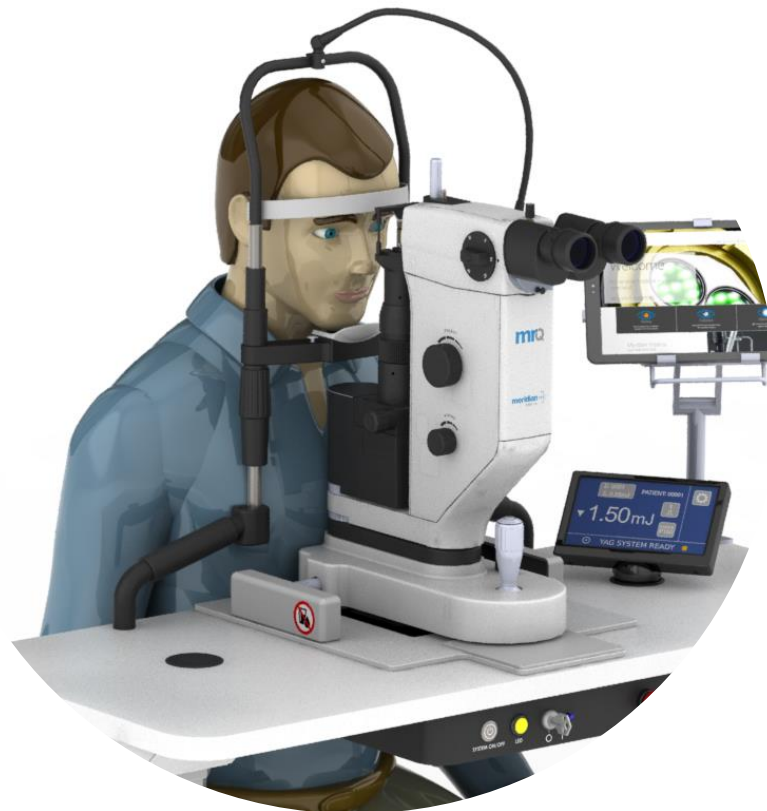
No.: Z12011017

Basic UDI-DI code: 383007498MTLSXX1XG

Intended medical use of MR Q SLT s:

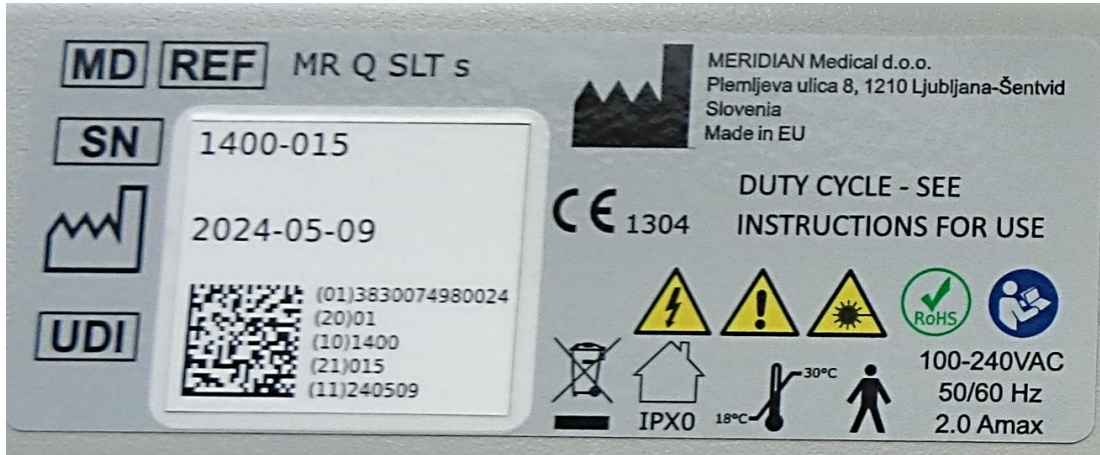
The MR Q SLT device incorporates two treatment modes and is intended for:

- in YAG photodisruption mode, to carry out:
 - posterior capsulotomy, to treat posterior capsule opacification,
 - iridotomy, to treat angle-closure glaucoma,
- in SLT mode, to carry out:
 - selective laser trabeculoplasty (SLT), to reduce intraocular pressure.



MR Q SLT ophthalmic medical device image

MR Q SLT s Serial No. 1400-015 labelling and packaging:



MR Q SLT s Serial No. 1400-087 labelling and packaging:

