ÓBUDAI EGYETEM

Kandó Kálmán Villamosmérnöki Kar
Elektronikai és Kommunikációs Rendszerek Intézet
Mikroelektronikai és Technológia Tanszék

SZAKDOLGOZAT

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Hallgató neve: **Török Réka Ágota**

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ÓBUDAI EGYETEM
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Óbudai Egyetem
Kandó Kálmán Villamosmérnöki Kar
Mikroeletronikai és Technológia Intézet

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.....
hallgató aláírása

MEDICAL USE OF VIRTUAL REALITY GLOVES

Virtuális valóság kesztyűk orvostechnikai alkalmazása

Török Réka Ágota
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1 Abstract

The aim of this thesis is to provide an overview on the medical use of a Virtual Reality glove and the steps that are necessary for certification.

We are examining the Quantum Meta gloves, a product of MANUS Technology Group, Eindhoven, from a certification and compliance point of view. In the recent past, multiple medical providers have approached MANUS with the request to use their gloves, and this thesis can help decide whether or not the gloves should be CE certified under the European Medical Device Regulation or not. The scope of the certification is VR gloves as rehabilitation and therapy device.

After auditing the company and reviewing the available technical documentation, we have a clear overview on the necessary improvement steps to be able to certify the product as a Class I. medical device under MDR.

Figure 1.1: MANUS glove (source [19]).

2 Introduction

2.1 Goal

Entering the medical market can be challenging even to the ones who already own an existing product sold for a different field. MANUS Technology is a VR glove company located in Eindhoven, The Netherlands who has been approached by medical providers asking if the gloves they make could be used as a medical device. As I found this topic very interesting, I happily volunteered to look into it and give a good overview to MANUS on what they can expect if they want to get their product CE certified for the medical field.

With this thesis, I would like to give an overview on what a VR glove is. Reading these pages you will get a good understanding on how VR came to life, and how it is used now. I will explain the technological background, the different approaches and how the MANUS gloves work.

In the second half, you will learn about the technical requirements of getting a certificate under the Medical Device Regulation (MDR) in the European Union, which is a must for selling medical devices in the EU market. MANUS is currently not certified, but due to the high interest in these gloves - also from the medical field - a good overview can give the company a better understanding on what improvements are necessary if they want to enter the market.

I will evaluate the Quantum Meta Gloves, which is one of the leading products of the company, from the aspect of use as a therapeutic medical device used for recovery after accidents, surgeries and other health modifying conditions. For this, audit results are compared with the MDR requirements. Improvement opportunities and risks are identified.

2.2 Literature Research

Let's look into the necessary definitions to have a better understanding on this topic. In this chapter, find a summary to have an overview on the history and the different uses of VR gloves and similar existing products.

2.2.1 VR Meaning

"VR, short for virtual reality is a set of images and sounds, produced by a computer, that seem to represent a place or a situation that a person can take part in"[5]

VR gloves are devices that can be worn like a glove. They're equipped with sensors and are designed to enhance the experience in VR environments. In some cases, VR gloves also have haptic feedback, which means that the users can interact with virtual objects, manipulate them with their hands and get a response. These gloves can be used in various settings, such as gaming, film industry, VR art, training simulations, also including medical training. These tools can give a great freedom and better practice, work or training opportunities by providing an environment for more immersive and effective experiences, allowing a presence and interactivity in virtual reality. Virtual reality gloves are usually equipped with one or more of the following features:

- **Gesture recognition:** based on the software support, some gloves can recognize hand gesture commands allowing the user to trigger actions without a physical controller.
- **Tracking sensors:** these sensors collect information on hand and finger movement and positioning. This tracking allows precise gestures to be replicated in the virtual world.
- **Wireless connectivity:** gives freedom to the user. With bluetooth connection, or other technologies, the user can move freely. In case of wireless connectivity, the battery lifetime and placement can be a restricting factor that is a challenge for product designers.

- **Haptic feedback:** force feedback or vibration can simulate the sensation of touching and therefore give a more realistic feeling of interacting with virtual objects.

2.2.2 Brief History of VR

[24] Throughout the centuries, humanity has always been interested in how the future will be and what technical innovations it will bring to make our lives better. The history of virtual reality dates from the middle of the 20th century, but the idea of depicting a world of expanded reality is as old as humankind itself.

The first steps towards a virtual reality coming to life started around the 60s: Morton Heiling created the Sensorama in 1956, patented in 1962 [24], a cinema world that is considered as the first predecessor of VR. It was similar to what we would call a 4D movie today: colorful 3D video with sound, smell and atmospheric effects, such as wind. Later he created the Telesphere mask, which is considered as the first Head Mounted Display (HMD) and was the basis of may similar products in the following decades.

Hand-in-hand with technological development, the 1980s were a real turning point in VR history: NASA has created the Virtual Environment Workstation shown in figure 2.1, which gave a solid base to many VR tools that we use today.

Figure 2.1: NASA Virtual Environment Workstation (source [2]).

The very first data glove, the Sayre glove, was made in 1977 and patented in 1982. This, and later many other tools enhanced the VR reality by giving an opportunity to bring a 3rd sense to the experience: after seeing and hearing, an active interaction was made possible by movement tracking and later with haptic feedback, giving a more immerse involvement in the experience.

The Nintendo Power Glove - despite the name - was a product made by Mattel in 1989, licensed to Nintendo. Since the use was limited and complicated to master, the glove was on the market for a short time only.

Figure 2.2: Nintendo Power Glove (source [3]).

After a successful and strong decade, the pace of VR innovation slowed down: due to the

technical costs, the availability of these tools remained very limited for the 90s and 2000s.

However, with the wider availability and reduced costs of electronic components, in the 2010s, a new chapter has started. In 2012, the Oculus Rift was released, opening a new chapter for VR possibilities.

We see more and more applications for artists, medical and military use, architecture, design and of course, gaming. My main focus was on gloves: by this time, due to the wireless technologies such as Bluetooth, and the availability of haptic gloves are available on the market, making the interaction of this world more reachable - literally.

2.2.3 Medical Applications

Besides the entertainment industry and military use, there is more and more attention on the possible medical use of data gloves. Some of the areas where such products can be used are in the telemedicine field, such as:

- Remote physical examinations
- Medical training and education
- Guidance for non medical personnel
- Physical therapy and rehabilitation
- Home health monitoring
- Psychological support, for example virtual treatment rooms for stress relief, PTSD and trauma treatment [26]
- Pain management solutions: VR-based devices may be used in pain management by providing distraction and relaxation techniques for patients during medical procedures or chronic pain management

2.3 Products on the market

2.3.1 VR Products

HaptX

HaptX offers the HaptX Gloves DK2, which are haptic feedback gloves designed for use in virtual reality environments. These gloves can be used in medical training simulations to provide a sense of touch and texture, enhancing realism. Uniquely to other products, HaptX gloves use a ‘ microfluidic skin’, force feedback exoskeleton and magnetic motion tracking together to provide word- leading excellence in the haptic glove field. Haptic gloves for virtual reality and robotics. [14]

Osso VR

Osso VR is a medical simulation platform that uses VR and haptic feedback gloves to train surgeons and healthcare professionals. It offers a range of surgical training modules that can be practiced using finger tracking gloves for precise hand movements. [25]

FundamentalVR

FundamentalVR combines VR technology with haptic feedback gloves to create a surgical simulation platform. Medical professionals can practice surgical procedures using realistic haptic feedback, enhancing their skills and dexterity. After contacting the company for an interview, I have learned that their product is not certified as a medical device because it is used as a training tool. Currently they do not use gloves but the Oculus set controllers for training. They do not plan to get a CE certificate under MDR in the next 5 years, but are closely working together with HaptX to use their data gloves in the future. [1, 23]

Most of the resources I could find were related to training or motion tracking in surgery. By measuring precise hand movements, the techniques of top surgeons can be analyzed, and even compared with novice surgeons. This also gives us a lot of improvement op-

portunities in future surgery training, which can result in the improvement of the overall medical education.

After a thorough research, I could not find a similar product used in a similar context. A similar concept certified in the market:

Perifit [22]

Perifit provides a product for pelvic floor exercise for women. The device can be connected to a smartphone app, offering interactive workouts to help tone and strengthen pelvic floor muscles. It is a biofeedback device that can provide real time data on performance: muscle contraction and relaxation.

This device is a muscle trainer and therapy device that is classified as Class 1 and sold on the EU market with a CE mark.

Figure 2.3: Perifit trainer and app (source [22]).

2.4 Technical implementation

Different brands use various technical solutions to reach the ideal way of working. See a few examples:

Optical systems without markers

For example: Kinect V2, Leap motion Contactless and affordable, which offers a great opportunity to be used widely. Line-of-sight restriction is present here too, and these products have limited accuracy to their more expensive counterparts.

Sensor gloves with bend sensors

For example: 5DT Data Glove Ultra, Cyberglove III. Setup is easy and quick. Usability is limited, as the gloves can measure only angles and no positions or velocity. Cleaning and hygiene is a key in the medical field, and with these gloves reaching the desired standard can be tricky.

Sensor gloves with IMUs

For example: IGS cobra gloves IMU stands for Inertial measurement unit. These units can track velocity, acceleration and the angular rates and orientation of the object it is used on. Each sensor is composed of 3 acceled=rometers, 3 gyroscopes and depending on the requirements, it can include 3 magnetometers.

However these gloves are quick to set up and the measurements are detailed, the usability can be limited by the following: hygienic standards can be difficult to reach, it is not suitable for spadtic hands and calibration motions are necessary which limits the areas of use. It uses magnetometers, so EMC requirements can be challenging to meet.

Different sensor technologies are used on the market: inertial, resistive or optical sensors. A big challenge in mechanical construction is to be size inclusive. Hand sizes vastly differ based on the person wearing them, and this raises questions regarding the efficacy and sensor placement.

Accuracy

Calibration method can be challenging with patients with limited hand gestures. The calibration algorithm often is very simple, not meeting the accuracy requirements of the medical field. There are many technical components involved in realizing an accurate and functional VR system.

2.4.1 Sensors used in MANUS Quantum Meta gloves

MANUS Quantum gloves use the combination of EMF and IMU sensors: Two of the most significant components are the Inertial Measurement Unit (IMU) devices which are used in the tracking of both headsets and gloves in 3d space, and ElectroMagnetic Field (EMF) sensors which are often used to track the relative positions of fingertips in glove applications. Both of these components are given a brief technical description below.

EMF implementation

There are many types of data gloves available which are used to track the pose and movement of a users' fingers using different implementations. In this case we discuss the use of magnetic fields, but other implementations can utilize changes in resistance as materials flex, or optical or acoustic measurement techniques. Each of these technologies must consider an additional challenge caused by variations in the size of the user's hand, which can affect placement of sensors relative to finger joints. Generally when using a magnetic field to track finger position, there are sensor coils placed at the fingertips or joints of the fingers, and an emitter which is used to produce a controlled magnetic field. One such glove [12] utilizes a magnetic field which is varied following a sinusoidal pattern. This is measured by the sensor coils in the fingers due to an induced current following Faraday's law. Using sensor coils in perpendicular orientations one can achieve an estimation of the position of the users finger tips [11].

IMU implementation

To track movement and orientation through space, IMUs use a combination of gyro-

scopes and accelerometers. IMUs provided for small electronic devices such as VR gloves often utilize Micro-Electromechanical Systems (MEMs) components which are often of the order of 20-1000 micrometers in size. There are various methods which can be implemented to measure linear and angular movement in MEMs systems. The MPU6050 is an example of a commercially available IMU that is often used within other devices. In the case of this device, linear movement in space is measured using a set of accelerometers along each axis of movement. The accelerometer is implemented using a 'proof' mass on a spring which moves within an array of capacitive plates, and in doing so creates a measurable change in capacitance [6]. To measure rotational movement, a Coriolis Vibratory Gyro [15] is used, which in this case is implemented using 4 oscillating proof masses and measuring the change in capacitance between them as they are affected by the Coriolis effect when under rotation [6]. However, with these measurements there is still a degree of noise or measurement drift due to technical implementation details, so the measurements are often post-processed in software using a technique such as a Kalman filter [20].

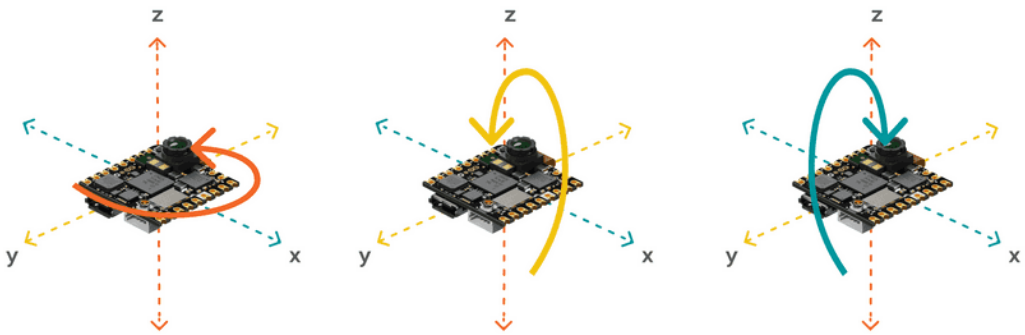

Figure 2.4: Gyroscope axis (source [22]).

2.5 Quantum gloves

MANUS was founded in 2014 in the Netherlands, and the first prototype dataglove was built in 2015 [17]. The startup participated at the Dutch Startup Bootcamp: Demo Day, which acquired leading development partners and enabled the company to speed up. In 2016, the first Development Kit Gloves (DK1) were released, with an upgrade to DK2 following the next year. DK2 is focusing on VR functionality. In 2018, the Prime gloves are released. This is a game changer and a big upgrade, as these data gloves already include haptic feedback. The following year the company is enriched with a skilled and substantial Software and development team, and the first Full Body Capture prototype, Polygon is built. In 2020, the first Open VR based professional tracker, Steam VR Pro is built, alongside with Prime II, an advanced version of the Prime glove. in 2022, a new version of Quantum Meta Gloves are released, leading the market.

In my thesis, I will take a look into the built and current use of this Quantum Metaglove, and give an overview on the potential medical use, then analyze the needed modifications to be used for a chosen purpose in the medical field: hand rehabilitation.

Figure 2.5: MANUS glove (source [19]).

Construction

MANUS gloves (shown in figure 2.5) use a combination of IMU and EMF sensors. The IMU sensor is responsible for orientation only, and not for location of the fingers. The glove consists of 5+1 coils: 5 on the fingertips and one in the middle. This center one on the back of the hand generates the electromagnetic field, and the movement of the fingers is measured by the movement of the 5 coils on the fingertips. These passive sensors are connected to the source via the cables that run at the back of the fingers. Their length can be adjusted based on user needs and preferences. The glove itself is cordless when used with a battery and can be connected to a computer with bluetooth, or if used without battery, with a shielded cable.

The sensors on the fingertips can be secured with the caps – they have silicone dots inside and outside for secure grip, or self-adhesive fingertip bands. These self adhesive bands are not reusable, but provide a natural feeling that can be useful for precise move-

ments. The user can decide which version they opt for - the reusable silicone fingertips are more affordable in the long term, but for cleanliness reasons, the bands can be a better solution. Due to the construction, the glove might inhibit certain movements, especially micromovements, and this has to be taken into account when using for rehabilitation.

By default, the gloves are battery operated. A battery can last 4 hours. If needed, use without a battery is possible, in this case the gloves can be connected to an energy source via cable. The weight of the glove is marginally influenced by the battery. This can be reduced by using an elastic band to secure the glove to the hand and using a cable to connect to an energy resource instead of a battery. The inverse kinematic system calculates the bone structure from the coil position using the freedom degrees and structure of a healthy hand according to human scales. The finger tracking happens with the calculation of the joint placements with a complex mathematical model.

Calibration

The glove is calibrated using the following steps [18]:

1. ”First, place your hand on a horizontal non-metal surface and close your fingers, but point your thumb outwards.
2. After that, raise your hand and close all fingers to make a fist
3. Lastly, touch the base of the palm of your hand repeatedly with your fingertips. Continue till the calibration step is complete.

After you finish the calibration on one glove, follow the same steps for your other hand. The calibration is stored on the gloves, so the next time you turn them on, you don’t need to calibrate again.”

From the above instructions, it is clear that the calibration guide was made for the average user, not taking into account the special needs users. In case of a medical use for rehabilitation, especially after serious injuries and surgery, the calibration either has to be modified or the glove be used without calibration. The gloves can be used without

calibration with a relatively good accuracy, although the model's scale and bones will not be completely accurate, the endpoints can be used as reference.

Cleaning

The glove fingertips have a silicone head that can be used for many hours. As these parts are inexpensive, however it is possible to wash them, frequent replacement is possible. The mesh glove is machine washable. Due to limited movement possibility - as this product is intended to be used for rehabilitation- the glove can be replaced with a rubber band. In this case the band can be washed as needed. The plastic parts can be sanitized with ethanol or other disinfectants. The lifespan of plastic parts clean with disinfectant agents is not tested yet.

Hardware requirements

Hardware requirements for connecting the glove and running the software:

- 2 Gb free space
- Windows 10/11
- Core i5-75000/Ryzen 1600
- 8GB RAM
- GTX 1060 / RX 580 - 6 GB VRAM

2.6 Use as a medical device: Hand therapy and recovery

Human hands are a complex interplay of anatomy and function. They consist of 27 bones and 29 joints each. Because of this complexity and the need for its dexterity in life, it is extremely important to maintain, and if necessary, restore the functions as much as possible.

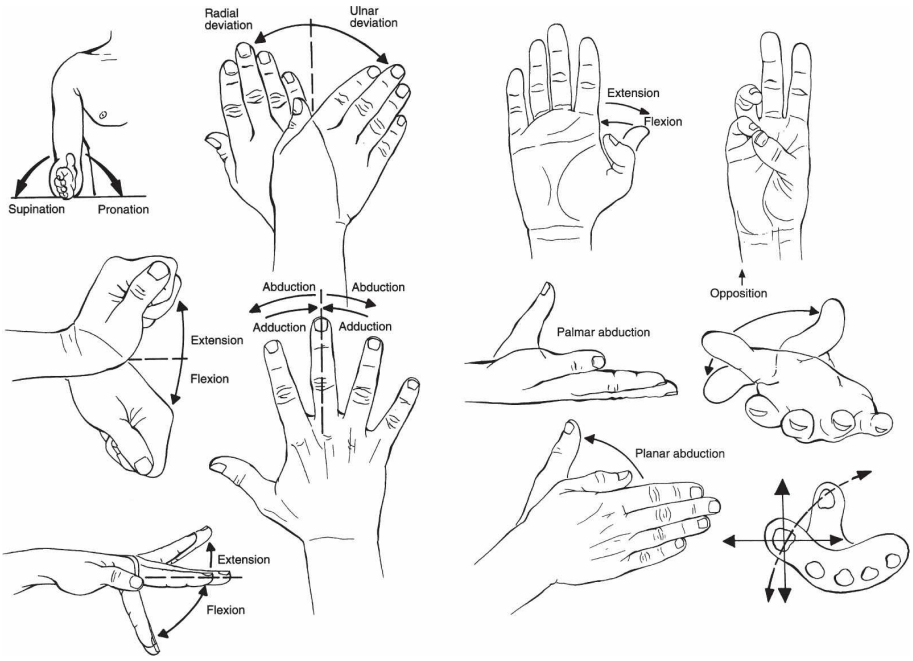

Figure 2.6: Hand motions (source [16]).

During my highschool years I had the chance to follow the work of a skilled physiotherapist who was working with children with hand injuries. The biggest challenge was always the home practice: no 14 year old wants to sit in one place and twist a rubber band or squeeze a soft foam ball dozens and dozens of times every day. Yet, stretching and movement is extremely necessary to regain the flexibility and motoric coordination skills.

Having the right tool to make the recovery time more fun can be a game changer, and MANUS gloves can bridge the current gap between need and available tools.

For a successful therapy, the followings are needed:

- Assesment: After a serious hand injury, regardless if surgery is necessary, a thorough evaluation of the hand's condition by a medical professional is necessary. This must include the range of motion, strength, sensation and any specific functional limitation.
- Customized treatment plan:
- Range of motion exercises

- Range of motion picture
- Strength training
- Sensory re-education
- Scar management
- Edema control
- Functional activities
- Pain management
- Patient education

Using a VR glove can help with completing personal goals during recovery. However the glove itself is not a measurement tool, it can store and provide data on the practice time and connected to the right platform, such as games, it can help to keep the patient motivated. The target audience for the gloves is the adult population and for the correct use, a frequent follow up with a medical professional is necessary.

3 Certification Process

In this chapter we take a look into what steps MANUS has to make to develop the organization and the QUANTUM gloves to be compliant. The following lists are made based on the EU MDR 2017/45 regulation [10]. After I specified the needs, I conducted an audit at MANUS, involving the product and its related processes. My observations are listed in the tables and when needed, explained longer after the tables. In order to place a medical device on the EU market, the product has to obtain the CE mark. The requirements for getting the certification can be found in the Medical Device Regulation, referred to as 2017/745. This regulation has replaced the previous European Medical Device Directive and became applicable in the European Union on the 26th of May in 2021. The Regulation is aiming to improve patient safety and enhance the quality and reliability of medical devices available in the EU market. It introduces stricter regulations on the approval, marketing, and monitoring of medical devices.

The transition from Medical Device Directive (MDD) to MDR brings a big change to the landscape from medical devices in the EU: the stricter regulations and additional requirements challenge the manufacturers, but also allows a better EU-wise overview on the products and their manufacturing and safety standards.

Compared to MDD, MDR has more detailed and expanded definition on medical devices, and this also includes products that were not considered medical devices under MDD. It also imposes stricter requirements on Notified Bodies. MDR, moreover, establishes Eudamed, a centralized European database for information on medical devices including registration, clinical data, and market surveillance data.

An online database is maintained by the European Commission [8].

3.1 MDR requirements [10]

MDR is a thorough and detailed regulation. In this chapter we find the steps data necessary to prepare for a certification.

Classification

Classification has to be done based on the intended use of the device. MDR distinguish 3 categories based on the available data: Class I, II a and b and Class III. Classification is discussed in more details in Conformity Assessment below.

Conformity Assessment

Opposed to MDD's annex II, III and IV, MDR introduces a more extensive assessment process, including stricter requirements for clinical evaluation and post-market surveillance. For Class I devices, self assessment is available with some exceptions. For Class II and b, and Class III. devices, a Notified Body needs to be involved for the certification. The list of Notified Bodies under MDR can be found at the NANDO website.

Technical documentation

Technical documentation must include the followings:

- Clinical data
- Risk management
- Design and manufacturing information
- Performance testing
- Biocompatibility
- Electromagnetic compatibility (EMC)
- Software validation
- Labeling
- Essential requirements
- Technical file

- Post-market surveillance plan
- Vigilance reporting
- CE marking
- Notified body

Unique device identification (UDI)

A more detailed explanation on how the identification has to be defined can be found at labeling information later.

Clinical evaluation

More rigorous clinical evaluation and investigation requirements, with a focus on the use of clinical data to support device safety and performance.

Post market surveillance

Strong emphasis on post-market surveillance, including Periodic Safety Update Reports (PSURs) and Summary of Safety and Clinical Performance (SSCP) documents

Declaration of conformity

The Declaration of Conformity (DoC) is a legal requirement. It is the manufacturer's statement that the medical device meets the essential requirements and it is in compliance with the MDR. It must be accessible for authorities. DoC can be issued in multiple EU languages, but based on the requirements, translation might be necessary for the product to be placed on specific EU markets. The DoC must include: Specific information such as the manufacturer's name and address, the device's description and details about its intended use and essential principles of safety and performance. Reference to applicable standards Identification of the Notified Body Signature and date

3.2 Certification process under MDR

However MANUS already sells their product with a CE mark [19], that is applicable only to the entertainment industry. In order to obtain a CE mark under MDR, additional tasks needs to be done. I conducted an audit at the company to find out the scopes for improvement that are necessary to get the gloves certified as a Class I. medical device.

3.2.1 Conformity Assessment

Compared with MDD, the MDR introduces new classification rules and reclassified some devices. This change ensures a more comprehensive regulation of products with medical purposes to enhance patient safety. For example: a software that is intended for general purposes but used for medical too, could be excluded from being classified as a medical device. Under MDR, a software that assists in the analysis, processing or interpretation of medical data, even if it doesn't directly perform medical function, may now fall under the scope of the MDR and require conformity assessment and compliance with the regulation.

Another example: certain products used for cosmetic or aesthetic purposes that didn't have a primary intended purpose to be used in a medical setting, might now be re-classified under MDR. This may include dermal fillers, which were sometimes regulated under different regulations in the past.

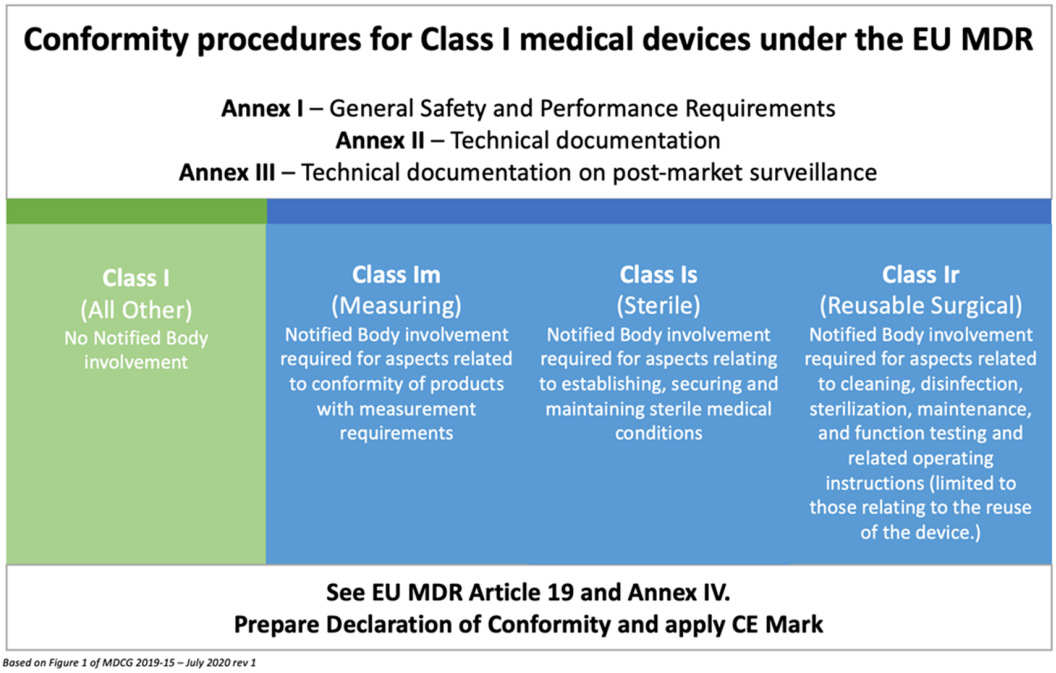

Figure 3.1: Conformity Procedures (source [21]).

Based on the classification, the involvement of a Notified Body might be necessary. Notified Bodies are involving experts to evaluate the safety of the products. If the design, risk assessment, manufacturing process and all other necessary requirements are met, the product may obtain the CE mark and be distributed on the EU market. The CE certificate is valid for 5 years, and in case of the involvement of a Notified Body, an annual follow-up audit is necessary. Changes have to be reported to the Notified Body to make sure the device still meets the requirements of MDR. For Class I products - since these devices have a simple design and pose minimal risk to patients – self-evaluation is available, therefore Notified Body involvement is not necessary.

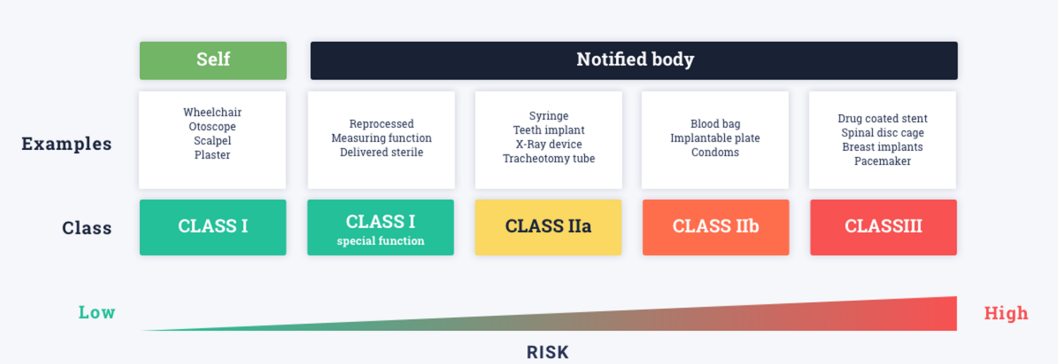

Figure 3.2: Classification vs Risk.(source [21])

In below table1, I summarize my findings during the audit. Since this thesis is open, it can't contain any confidential information, therefore the followings are the main findings and scope for improvement and do not contain specific details regarding the company, nor their products.

Intended Use	Applicable MDR section (Annex VIII)
What is the primary purpose?	Hand therapy and recovery
How is it intended to be used in a medical context?	The glove is intended for the adult population and is to be used with the accessory software. The main purpose is to provide the possibility to the patient to connect the glove to games, and make the recovery exercises more enjoyable.

Table 1 – continued from previous page

Mode of action	'Active therapeutic device' means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability 'Active device intended for diagnosis and monitoring' means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities
Risk assessment	Risks have to be identified according to ISO 14971. It is currently not done by the company
Duration of use	'Transient', that means normally intended for continuous use for less than 60 minutes
Invasive or non-invasive	Non-invasive
Combination Products	Software, which drives a device or influences the use of a device, is an accessory therefore does not need to be certified or evaluated (MDCG 2019-11)
Active or non-active	It is active, and works with either a battery or can be connected to an energy source via cable
Diagnostic or therapeutic	Therapeutic
Comparable devices	No exact correspondence is certified on the market. The closest: a pelvic floor muscle trainer connected to a phone app is Perifit, and it is certified as a class I device.

Table 1: Audit findings - Classification

Hand recovery and therapy devices depending on their risk level and intended use, may be classified as Class 1 medical devices under MDR. Class 1 devices are considered low-risk, and their conformity assessment is done by self-certification by the manufacturer. Based on the above information, the Quantum gloves used in a medical context as a therapeutic device, with no haptic feedback and no measuring function, would be class 1 under MDR.

Depending on the requirements of individual EU member states, the device or the company has to be registered with the competent authorities where the products are marketed.

3.2.2 Technical Documentation

In order to be able to self-evaluate,the company needs to prepare the technical documentation following the points of MDR. Therefore, it must include:

Clinical data such as:

- Clinical evaluation plan
- Clinical evaluation report
- Post-market clinical followup (part of PSUR as well)
- Use of Clinical Data

This means expert involvement, research and working together with hospitals and other medical organizations to evaluate the usability and potential risks of the product.

Periodic safety update report (PSUR)

After getting certified, it is mandatory to monitor the market and collect information on the possible new information, be it a new research or a safety notification from a similar manufacturer. The PSUR involves the followings:

- Post market surveillance (PMS), involving vigilance and Corrective Action and Preventive Action (CAPA)
  - volume of sales (86.1)
  - size and other characteristics of the population using the device (86.1)
- PMS: vigilance and CAPA
  - Information concerning incidents and serious incidents (article 87, Annex III MDR)
  - Information from trend reporting (88, annex III MDR, non-serious incidents and expected undesirable side effects)
  - Signal identification
  - Information from Field Safety Corrective Actions (FSCA) (87, Annex II MDR)
  - Preventive and/or corrective actions (CAPA) (83.4, 86)
- Post-market clinical followup (PMCF) report
  - PMCF plan
  - Data collection:
    - Feedback and complaints from users, distributors and importers
    - Scientific literature review of relevant specialist or technical literature
    - Public databases and/or registry data
    - Publicly available information about similar medical devices
    - Market activities and usability surveys (final user surveys and distributor survey)
  - Other data sources
- Update: this includes the happenings and changes from within the organization. PMS
- Risk management
- Trend report
- Design and manufacturing
- SSCP

- Clinical evaluation
- CAPA
- Usability
- Technical documentation
- Benefit/risk profile
- Summary and findings
  - Validity of the collected data
  - overall conclusion from the analysis of the collected data
  - actions taken by the manufacturer

Audit findings

The required technical documentation is shown below in table 2.

Audit point	**Audit finding**
Design specifications, drawings	Design is available and was made in-house Detailed design is documented to the component level. Component datasheets available. Traceability of design changes is available. Parts are partially bought from suppliers off the shelf, partially made to order and partially made in-house. During Design, no medical standards were taken into account. It is necessary to revise all documentation from the perspective of applicable standards.

Table 2 – continued from previous page

Manufacturing information	Manufacturing information available. Comprehensive manufacturing specifications and procedures: work instructions are clear and detailed. Version tracking/change management on the documents. Supplied components traceable to the supplier. Datasheet available. Made-by-order components designed in house. Descriptions of manufacturing processes are available. Incoming goods are checked. Manufacturing includes assembly, soldering, cleaning and packaging. Every product is tested during and after assembly. Traceability is not available to the base material level. Repair database available.
Materials and components	Product is currently on the market as consumer electronics, complying with applicable standards. Materials and components have to be checked if complying with medical standards and directives.
Traceability of materials throughout of the manufacturing process	Available to some extent. Components with serial numbers are associated with the end product. Traceability to base materials/batches has to be implemented.
Software	Software is present, version tracking is available. Software is made in-house, and updated when necessary. Certification of the software is not necessary, according to MDCG 2019-11. See more below this table.
Sterilization and packaging	Sterilization not applicable. Packaging is according to standards.

Table 2 – continued from previous page

Labeling information including symbols, instructions, and any warnings	Labeling according to consumer electronics specifications. Labeling has to be harmonized with EU regulations and applicable ISO standards. Necessary instructions and safety labels have to be added according to requirements for medical devices. User manual videos available on Youtube. A quick start guide is available with a link to the website resources and how to get the software. Written manuals have to be included in the languages of the countries where the product is marketed. Local regulations have to be checked on distribution and sales requirements. Compliance with labeling requirements specified in MDR and correct use of CE mark has to be checked.
Validation and verification	Validation and verification of the product and processes needs to be carried out in order to ensure compliance with MDR. This must involve the design and manufacturing process, including testing. Records must be kept and stored according to the regulation.
Evidence that the device meets its intended purpose	Consultation with medical professionals, usability, clinical study of the product and similar product has to be carried out.
Biocompatibility	Biological risk assessment has to be carried out.

Table 2 – continued from previous page

Electromagnetic compatibility	IEC 60601-1-2 Electromagnetic compatibility. This part of the standard involves the requirements regarding EMC that ensure that a medical device does not interfere with other medical equipment and is not susceptible to interference. However the Quantum gloves are not yet evaluated under IEC 60601-1-2, they already obtain a CE certificate under the Manus Meta-gloves Quantum do comply with the IEC/ EN 55032, Class B, RF emission requirements. As such, it also fulfills the requirements of EN/ ETS 301-489-1. EMC test according to IEC 60601-1-2 has to be carried out.
Risk management	Risk management is currently done according to the consumer electronics standards. To manufacture as a medical device, a risk assessment has to be carried out in accordance with ISO 14971
Design and manufacturing	See in the next table. A review is necessary on current part and their usability. For example: for cleaning, instead of the current 3D printed cover, an injection molded sensor cover would be necessary so that it can be cleaned better. Depending on the IP requirements, charging points should be able to be covered.

Table 2: Audit findings - Technical Documentation

3.2.3 Software

I was mainly focusing on the use and certification of the MANUS Quantum glove. for use as a rehabilitation tool, however, software is necessary. It is up to the company whether they would like to use a software made for them, or cooperate with an existing product.

We differentiate 3 categories for medical device related software:

- SaMD - Software as a medical device
- Software driving or influencing the use of a device
- An accessory of a hardware medical device.

This is defined as follows in the MDCG 2019-11 guide, which is applicable for Medical Software [9]: ''Software which is intended to drive or influence the use of a (hardware) medical device and does not have or perform a medical purpose on its own, nor does it create information on its own for one or more of the medical purposes described in the definition of a medical device or an in vitro diagnostic medical device. This software can, but is not limited to: (a) operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device (b) or supply output related to the (hardware) functioning of that device ''

Since the rehabilitation glove does not measure, process or analyze any medical data, and the software does not affect the use of the device, the accessory software is not considered as a medical device and therefore does not falls under the certification criteria of EU MDR 2017/745.

3.2.4 Labeling - GMDN, UDI and CE mark

Under MDR, a new naming convention is established. The goal is to have an uniform convention on the EU market. This can result in a more transparent product market.

The Global Medical Device Nomenclature (GMDN) uses a hierarchical naming convention to categorize and name medical devices. It typically follows a structure of four levels:

Segment, Family, Class and Generic Descriptor. Each level provides more specific information about the device. GMDN codes help to categorize and classify medical devices.

The Quantum glove used in the previously mentioned context falls under the "Physical Rehabilitation Devices" category.

Based on the GMDN website, the code for term "*Virtual-display rehabilitation system, non-supportive*" is: 60926. The definition of this product is: "*An assembly of devices intended to be used in the home to provide non-gravity-compensating rehabilitation therapy for neuromuscular/musculoskeletal conditions affecting the back/trunk/limbs (e.g., impaired limb function) through patient interaction with a videogame-like display prompting repeated motion of a body part (e.g., arm, hand, leg) for functional improvement; it may also provide performance feedback. It does not provide weight support and is based on motion-sensing devices [e.g., battery-powered patient-worn infrared (IR) glove, motion tracking heel pad, movement tracking camera, software] that communicate (e.g., wirelessly) to provide a virtual-display interface.*" [13] This gives us the GMDN code.

The UDI system incorporates the GMDN code as a part of the unique identification for each device [7]. The UDI code includes both the Device Identifier (DI) specific to the device model, and a Production Identifier (PI) which includes information like LOT number and expiration date.

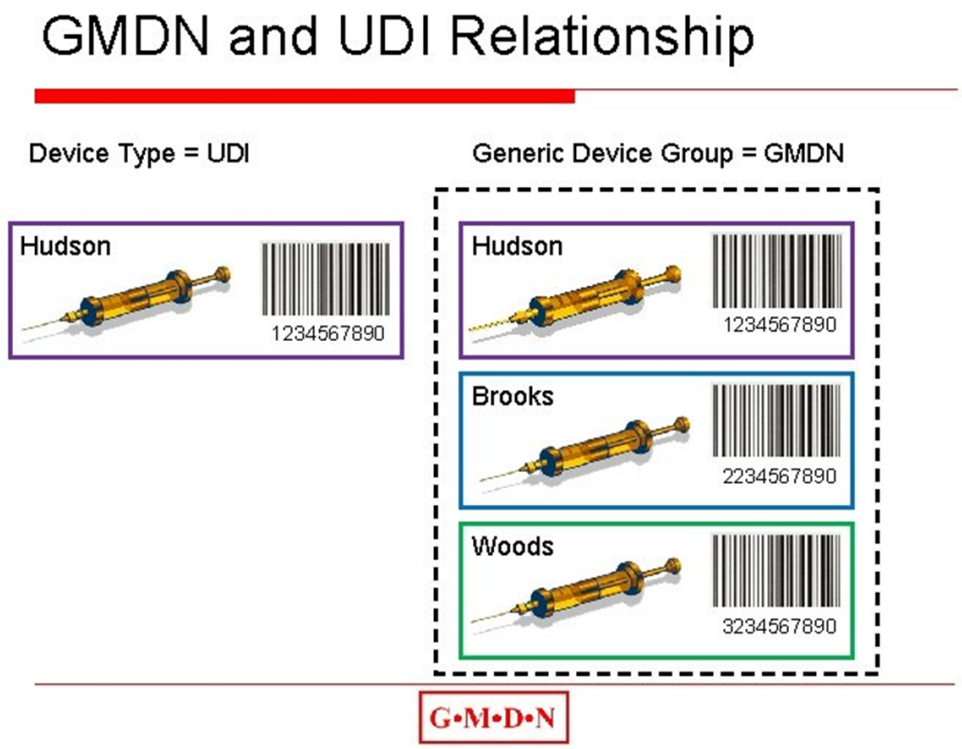

Figure 3.3: GMDN UDI relationship illustrated (source [7]).

Figure 3.4: Barcode (source [7]).

Manus has to define the necessary UDI codes.

CE Mark

After obtaining the rights to use the CE mark, the manufacturer has to make sure to use the logo in accordance with the specifications. The CE mark shall be used according to these measurements:

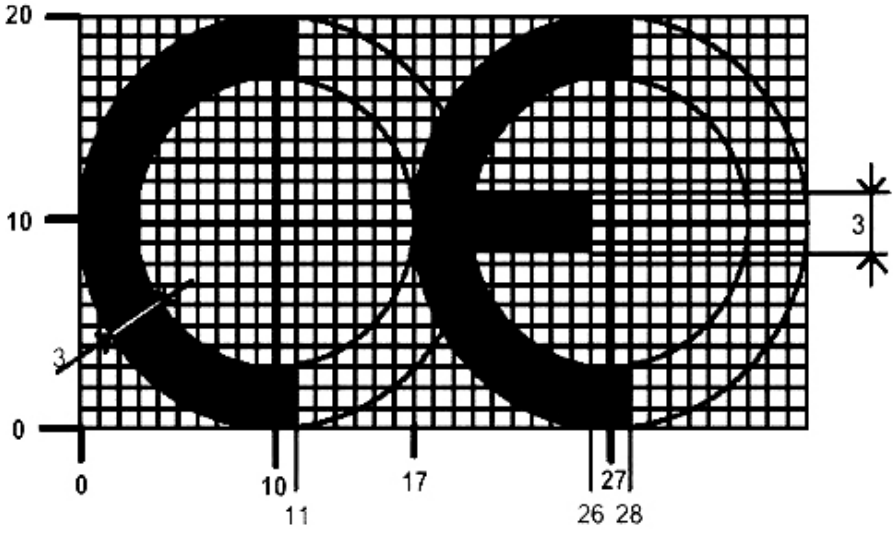

Figure 3.5: CE Mark Dimensions (source [4]).

3.3 Quality Management System

Although the ISO standards are not mandatory under MDR, they are highly recommended and often used as a way to meet the essential requirements of the regulation. ISO 13485:2016 defines the quality management system requirements for medical device manufacturers. It requires the following (and even more) to be documented. For Risk assessment, ISO 14971 can be used. This thesis is not focusing on the 14971 standard.

Requirements	**Readiness**
Quality manual: it shall include the quality management system structure	Processes are well defined and written down. No quality manual available. Production steps, work instructions are defined and written down. ROHS, REACH and multimedia? CE compliant. No ISO certified QMS within the company. Quality manual in compliance with standard has to be done.
Quality policy: the organization's commitment and compliance with the standard	Quality policy is available, but not according to 13485. A review is necessary.
Procedures	Needs to be documented for design and development, risk management, production and post-market surveillance
Work instructions	Well maintained instructions are necessary to provide a constant and reliable workflow. Current work instructions are detailed and cover the production steps. Further instructions are necessary to cover the additional tasks that are related to the certification procedure.
Records	Such as management reviews, corrective and preventive actions, and product inspections: product related records are available and maintained. Internal audits and management reviews need to be recorded.
Risk management documentation as required by ISO 14971	Currently done according to other standards, has to be completed.

Table 3 – continued from previous page

Requirements	**Audit finding**
Supplier and service provider documentation	Supplier evaluation is not done for subcomponents suppliers. Final assembly is within the company. Critical components - cables and PCB: suppliers have all the certificates in place. These suppliers also provide medical suppliers, therefore a check is necessary but no need for new suppliers.
Change control records: any change made in products, processes or the QMS	Product and production related records are well maintained, revision change controlled. Other QMS related changes need to be recorded in a more organized manner.
Complaint handling records	No stock on old parts is available. The complaint handling process is well defined and the records are maintained and kept. A generic complaint sheet is available for recording all necessary information. Test records of service items as well as production batches are available, and status is recorded with pictures as well. Incoming check is done according to internal agreement - depending on the component on a 100% or as sampling is defined.
Training records	No training records are kept at the moment, training is done as a part of onboarding and later on demand or if necessary. To comply with ISO 13485:2016, the company needs to keep training records including a proof of successful mastering of the skills.

Table 3 – continued from previous page

Requirements	**Audit finding**
Document control	Document control is limited at the moment. Version tracking, change control and archiving is available, but an extended list and control of available documents is necessary.
Internal audits	At the moment, internal audits and management reviews are held as needed. Following the guidelines of ISO 13485:2016, even if MANUS is not certified under this standard, the records have to be saved and the necessary actions followed up.
Management review records	See above
Records of monitoring and measurement	Every product: test is recorded – traceable, if not pass, goes back to production and gets repaired and then re-tested. Monitoring and measurement data is available for manufacturing, testing and repairs.
Risk management files	An FMEA was implemented : a framework was set up. Risk management and files needs to be updated according to ISO 14971:2019 standard

Table 3: Audit findings - Quality Management System

4 Summary

Virtual reality can improve work and life quality in many areas. One of these is the medical field, where the introduction process is one of the slowest. It is due to the high regulations and complex requirements that are necessary to provide patient safety and usability.

Currently there is no similar product on the market classified under MDR as a rehabilitation tool. This gives a great opportunity for MANUS technology to enter the market gap. In order to do so, the Quantum Meta Gloves need to be certified under EU MDR 2017/45. When certified as a Class I. device, self-evaluation is possible.

To define the gaps between the current way of working and product qualifications and the need for MDR compliance, an audit has been carried out. The results cover the quality management system, the current processes and the technical documentation of the device. The audit results also include the scopes for improvement.

One of the main improvement points is carrying out a risk assessment according to the applicable medical standard. Additional procedures have to be defined and implemented and modifications necessary to ensure the safety and compliance of the Quantum Gloves.

Overall MANUS is in a good position and due to the maturity of the organization and the qualifications, completing the additional requirements, the Quantum Meta gloves have a great chance to enter the medical field and bring innovation to the word of hand rehabilitation.

5 Összefoglaló

Az alábbi szakdolgozat célja, hogy egy VR kesztyű orvostechnikai alkalmazására példát hozzon és bemutassa a tanúsítás lépéseit.

Az eindhoveni MANUS Technology Group-pal együttműködve az egyik terméküket, a Quantum Meta kesztyűt vizsgáltam abból a szempontból, hogy milyen követelményeknek kell megfelelnie a piacra kerüléshez, ha orvostechnikai eszközként szeretné a cég tanúsíttatni.

A céget a közelmúltban több forgalmazó és intézet is megkereste a lehetséges orvostechnikai alkalmazásokat illetően. Ezért a dolgozatban arra szeretnék választ adni, hogy hogyan lehet a Quantum Meta kesztyűt mint rehabilitációs-terápiás kesztyűt tanúsíttatni. Az eszköz célja így sérülések, műtétek utáni rehabilitáció követése vagy izgalmasabbá tétele lehet.

Az Európai Unióban érvényben lévő 2017/45 orvostechnikai rendelet (Medical Device Regulation - MDR) szigorú követelményeket állít a gyártó cégekkel szemben a tervezés és gyártás mellett a tanúsításra vonatkozóan is. A dolgozatban azt vizsgáljuk, hogy egy MDR szerinti I. kategóriába (Class I.) sorolt eszközre milyen követelmények vonatkoznak. Ehhez a MANUS-nál auditot folytattam, aminek az eredményeit részben olvashatjuk a dolgozatban. Az audit során nem csak a termék dokumentációját, de a cég jelenlegi működését és a gyártási folyamatot is mintavételeztem.

A dolgozat első felében betekintést nyerhetünk a Virtuális Valóság (Virtual Reality - VR) és az adatkesztyűk (data gloves) rövid történetébe. Ezután összegzést olvashatunk a jelenleg a piacon található orvostechnikai VR eszközökről.

A dolgozat második felében bemutatom a MANUS Quantum Meta kesztyűt, annak működését és felépítését. Ezután végigvesszük az MDR szerinti tanúsítás legfontosabb lépéseit, majd azt, hogy a cég miben kell a jövőben fejlődjön, hogy megszerezhesse a CE jelet. Ez magába foglalja a termékre vonatkozó követelményeket, a felhasználás

körülményeit, a csomagolást, címkét és használati utasítást. Itt kerül sorra a műszaki dokumentációnak és a cég belső működésének felülvizsgálata is.

Az MDR követelményeit az audit eredményével összevetve kirajzolódik a kép, hogy milyen területeken szükségesek fejlesztések, milyen veszélyekkel kell számolni.

Az audit eredményei alapján a Quantum kesztyűt és a minőségirányítási rendeszert is fell kell készíteni az orvostechnikai tanúsításra és pótolni kell a kockázatelemzést és a klinikai vizsgálatokat. Módszereket kell meghatározni a PMCF és PSUR elvégzésére és biztosítani kell, hogy a megfelelő szakértelemmel rendelkező munkaerő rendelkezésre álljon. Mivel a kesztyű jelenleg is piacképes szórakoztató elektronikai területre tanúsítva, a cégnek jó gyakorlata van minőségirányításban és fejlesztésben, így ezek a lépések sem okoznak majd problémát.

Glossary

CAPA Corrective Action and Preventive Action

DoC Declaration of Conformity

EMF ElectroMagnetic Field

GMDN Global Medical Device Nomenclature

HMD Head Mounted Display

IMU Inertial Measurement Unit

MDD Medical Device Directive

MDR Medical Device Regulation

MEM Micro-Electromechanical System

PSUR Periodic Safety Update Report

SSCP Summary of Safety and Clinical Performance

UDI Unique device identification

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