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Reprocessing of medical devices

Possibilities and limiting factors

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Abstract

Reprocessing of medical devices
Possibilities and limiting factors

The possibilities and limiting factors for reprocessing single use devices (SUDs) and reusable medical devices (RMDs) have been investigated and several issues were identified. To solve these issues, it is proposed to redefine used SUDs as waste material. Anyone reprocessing used SUDs to make them available again for use should be defined as a manufacturer that uses waste material to produce new medical devices. Therefore, the reprocessor becomes a manufacturer and has to comply with all the requirements of the Medical Device Directive, including CE-marking of the devices, performing risk analyses, notified body involvement, etc. For the user, this has the advantage that no matter whether they use a new device from an original manufacturer or a renewed device from the reprocessor, the safety of the device is guaranteed through the CE mark.
Reclassifying RMDs based on their intended use instead of as class I as given in classification rule 6, will result in most devices being in a higher risk class. For devices in a higher risk class than class I, a notified body has to be involved in reviewing the design of devices, including the reprocessing instructions. This should force manufacturers to validate their reprocessing instructions, leading to improved reprocessing instructions.

Key words:
reprocessing, medical devices, MDD, Medical Devices Directive, legislation

Rapport in het kort

Hergebruik van medische hulpmiddelen
Mogelijkheden en beperkingen

De mogelijkheden en beperkingen van het opwerken van gebruikte hulpmiddelen voor eenmalig gebruik (SUDs) en herbruikbare medische hulpmiddelen (RMDs) zijn onderzocht. Daarbij zijn enkele problemen naar voren gekomen. Om deze problemen op te lossen wordt voorgesteld om gebruikte SUDs te classificeren als afvalmateriaal. Degene die SUDs opwerkt om deze weer aan te bieden voor gebruik zou moeten worden beschouwd als fabrikant die afvalmateriaal gebruikt om nieuwe medische hulpmiddelen te fabriceren. De opwerker moet dan voldoen aan de eisen uit de Medical Devices Directive, inclusief CE-markering voor de hulpmiddelen, uitvoeren van risicoanalyses, beoordeling door een aangemelde instantie etc. Voor de gebruiker betekent dit dat, ongeacht of een nieuw hulpmiddel van de originele fabrikant wordt gebruikt of een opgewerkt hulpmiddel van de opwerker, de veiligheid van het hulpmiddel is gegarandeerd door de CE-markering.
Het herclassificeren van RMDs op basis van de beoogde toepassing en niet als klasse I zoals classificatieregel 6 aangeeft, zal ertoe leiden dat de meeste RMDs in een hogere risicoklasse gaan vallen. Voor hulpmiddelen in een hogere risicoklasse dan klasse I, dient een aangemelde instantie het ontwerp van hulpmiddelen, inclusief de instructies voor hergebruik, te beoordelen. Hierdoor zullen fabrikanten gedwongen worden om hun instructies voor hergebruik te valideren, wat zou moeten leiden tot verbeterde instructies voor hergebruik.

Trefwoorden:
hergebruik, medische hulpmiddelen, Besluit medische hulpmiddelen, wetgeving

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Contents

1 Definitions and abbreviations

MDD (medical devices directive):
European Directive regulating the marketing and putting into service of medical devices.

OEM (original equipment manufacturer)
The manufacturer that produces the medical device and places that medical device on the market.

Reprocessor
Person or legal entity that reprocesses used SUDs for the purpose of being used again, including hospitals.

RMD (reusable medical device)
Medical device that is designated or intended by the manufacturer for use during consecutive medical procedures and for which the manufacturer has specified the necessary reprocessing procedures.
Note: The number of allowable reuses may be limited as indicated by the manufacturer.

RSUD (reprocessed single use device)
SUD that has been cleaned and sterilized for the purpose of being used again, on the same patient or on another patient.

SUD (single use device)
According to the definition in the MDD, ‘single use device’ means a device intended to be used once only for a single patient. To prevent discussion on the phrase “to be used once only”, which could be misinterpreted so that during a surgical procedure it is not allowed to use for example a single use suction cannula more than one time during the procedure, a broader definition is used in this document: Medical device that is designed or designated by the manufacturer for use during a single medical procedure on a single patient and that is to be discarded after the procedure.
Note: Single used devices are also called ‘disposables’.

User
The person or legal entity in an organisation providing healthcare, that is ultimately responsible for the use of a medical device in that organisation (eg board of directors in a hospital or the GP in a GP’s office).

2 Introduction

2.1 Objectives and scope

The Department of Pharmaceutical Affairs and Medical Technology of the Dutch Ministry of Health, Welfare and Sports requested substantive support for the pro-active development of a Dutch strategy for guaranteeing the safety and quality of reprocessed single use devices (RSUDs). This is to prepare the Dutch participation in the development of European legislation on this subject.
The following research question was posed:
"What are the possibilities and limiting conditions for the re-use of single use devices?"
As the reprocessing of reusable medical devices (RMDs) is also known to pose risks and the intentions of European reprocessing legislation go beyond the reprocessing of single use devices only, the reprocessing of RMDs is also considered in this report.

2.2 Single Use Devices

Single use devices (SUDs) play an important role in healthcare. Many of the surgical interventions could not be performed or would be considerably more invasive and riskier without the use of SUDs. The major advantages to the use of SUDs are:

- SUDs enable technically complex operations to be performed (e.g. heart catheterization), for which no RMDs are available;
- the device is ready for use;
- the quality is constant;
- there are no additional costs for reprocessing.

It is clearly the intention of the OEM that the devices are discarded after use.

2.3 Revision of the MDD

In the revision of the Medical Devices Directive (MDD)[1], the reprocessing of medical devices has not been elaborated yet. Article 12a states: "The Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community. In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection." There has already been a questionnaire of the European Commission on this topic[2].
The reprocessing of SUDs is a topic of debate in Europe. The major parties in the debate are the manufacturers of medical devices, united in Eucomed, that state that single use devices can not be reprocessed at all[3], and the reprocessors of medical devices, united in the European Association for Medical Device Reprocessing (EAMDR) that emphasize that reprocessing can be done safely and can reduce costs[4]. Both parties are clear in their standpoints and provide valid rationales for their views.

[1] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.
[2] Synthesis document, outcome of the first public consultation on the reprocessing of medical devices, European commission, Enterprise and industry Directorate general, http://ec.europa.eu/enterprise/medical_devices/synthesis.pdf
[3] http://new.eucomed.org/Home/portal/press/focus_on/2006/200603mtf50.aspx
[4] http://www.eamdr.org/

A common argument in favor of reprocessing is that SUDs add to the amount of waste generated from healthcare. This argument will not be discussed in this letter report as the authors are not in the position to balance all the environmental implications of reprocessing versus discarding used devices.

3 Designating a product as single use device

3.1 Conclusion

The main criteria for designating a product as a SUD are the materials and the construction of that device.

3.2 Materials and construction

3.2.1 Deterioration during use

Many SUDs are made from plastic materials which allow them to be mass produced at limited costs and/or give them specific qualities (e.g. the flexibility of long catheters for stent placing). Although plastics have many excellent properties, which allow the production of complex SUDs, they may not be durable. Where this is perfectly acceptable if the device is used only once, it might be a problem when it is reused, since the material's properties may deteriorate rapidly once the device is used or reprocessed.
This is the case with catheters fitted with an inflatable balloon. The material of the balloon stretches during use and limits any further reuse. Depending on the intended use, surfaces that come into contact with patient material may be coated to increase the haemocompatibility and biocompatibility. These coatings may dissolve or sustain damage during use which may limit their further use.
In view of this, subsequent reuse might give a higher and/or unpredictable risk of device failure.

3.2.2 Reprocessing

The materials and construction of SUDs might be unable to withstand the cleaning and sterilization processes. The mechanical, thermal and chemical impact of the processes can influence the properties of the materials and the construction. This can influence the mechanical strength of the product and its biocompatibility. Surface coatings may disappear when the device is washed. Special attention should be given to the joints between the different parts of the product. These joints are known to be vulnerable. Weakening of these joints can jeopardize the safety and functionality of the product; parts of the device may detach during use and remain in the patient.
The cleaning of the device is influenced by the materials used and the accessibility of the surfaces to be cleaned. For example, the cleaning of a single ended open lumen and edges can be problematic.
Since the device is not designed to withstand any reprocessing, it may damage easily when handled without care.
Reusable lumened medical devices are constructed to allow flushing with a detergent solution.

3.3 Economics

Another reason for designating a product as SUD can be that the manufacturer can not afford to, or does not want to pay for validation of a reprocessing procedure. This can be the case when a product is sold in limited numbers.
Allegedly, there are products marketed as SUDs in some countries and as RMDs in other countries, without significant differences between the two types of product. However, the authors are not aware of specific examples of such products and can therefore not elaborate on this issue.

4 Financial aspects of reprocessing SUDs

4.1 Conclusion

Financial considerations are the main reason for reprocessing SUDs. Although there might be a financial benefit to reusing SUDs, all aspects and their associated costs need to be taken into account.

4.2 Calculating costs for reprocessing SUDs

SUDs are often expensive medical devices. By reusing a SUD, the costs for the device could be divided over multiple patients thus providing a cost reduction of the medical procedure.

In order to establish whether cost reductions are possible, the following costs and considerations need to be taken into account:

a. the purchasing costs of the device;
b. the allowed number of reuses before the device must be discarded;
c. the costs for developing and validating the cleaning, disinfection and sterilization process, including the costs for evaluating the biological, physical, chemical, mechanical and toxicological properties of the reprocessed device;
d. the actual costs for performing the reprocessing, including packaging;
e. the costs for logistics;
f. costs arising from the liability when the device fails, leading to injury or death of a patient;
g. costs arising from damage of the reputation of the physician and/or the health care facility as a consequence of a RSUD failing, leading to injury or death.

5 Reprocessing issues

5.1 Conclusion

The reprocessing of SUDs requires suitable equipment, knowledge, skills and resources, which are unlikely to be present in a hospital. Therefore, adequate reprocessing of SUDs is nearly exclusively the domain of specialized reprocessing companies.

5.2 Design of medical devices

The main problem is the cleaning of medical devices. Problems occur with devices containing internal or moving parts, which cannot be adequately cleaned using standard equipment. Because the remaining contamination is not visible from the outside, this is only noticed when the functionality of the product deteriorates and the cause of this deterioration is investigated. The instructions for reprocessing of RMD in most cases do not contain specific information on testing the cleanliness of the device; they only recommend the process parameters (see also 5.3).
Moreover, the materials used for SUDs are not commonly reprocessed and therefore, there is no or only limited information available on the effects of reprocessing these materials. Therefore, more elaborate studies are necessary to establish the compatibility of these materials with the reprocessing procedures.

5.3 Instructions for reprocessing

The MDD requires the manufacturer to supply "*if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.*" (Essential requirement 13.6.h). The harmonized standard EN ISO 17664 has been developed to lay down the information that needs to be present in the instructions for resterilizable medical devices[5]. This standard also requires the recommended reprocessing procedure to be validated. Moreover, the manufacturers should be aware "*of the training and knowledge of procedures, and of the processing equipment available to the persons likely to be responsible for processing*".
A previous RIVM-investigation revealed that many instructions supplied with resterilizable medical devices contained insufficient information for an adequate reprocessing procedure[6]. Nevertheless, most users will reprocess these devices using the available means and standard procedures, drawing on their experience with similar or other devices. It must be noted that validation of the cleaning and sterilization procedures on a product level are not feasible in hospitals, which makes it essential that the recommended validated reprocessing procedures are compatible with the standard reprocessing procedures in hospitals.
A complicating factor is the fact that the reprocessing staff in hospital is frequently faced with a fait accompli; the RMD is bought by the hospital without checking whether the devices can be reprocessed with the standard procedures available in the hospital. Before purchasing a RMD, a hospital should confirm that this particular medical device can be adequately reprocessed using the available equipment and procedures in that hospital.

[5] NEN-EN-ISO 17664: Sterilization of medical devices -Information to be provided by the manufacturer for the processing of resterilizable medical devices (2004)

[6] Angaben zur Wiederverwendung: Caveat emptor!/Instructions for Reuse: Beware when Buying, A. van Drongelen, A.C.P. de Bruijn, Zentr Steril 2006; 14 (1), 30-36

Although providing insufficient information concerning the reprocessing procedures can be considered a violation of the MDD, this is rarely reported to the competent authority. The above mentioned RIVM investigation[6], in which examples of instructions for reprocessing provided by Dutch hospitals were evaluated, indicates that inadequate instructions for reprocessing are not uncommon.
In 2007, only one Dutch hospital complained to the Dutch Healthcare Inspectorate about inadequate reprocessing instructions provided with a reusable surgical instrument. The Inspectorate urged the manufacturer to revise the instructions. The manufacturer developed new reprocessing procedures incorporating cleaning in a washing machine instead of manual cleaning. These new procedures are in line with the requirements in the international standard EN ISO 17664. This example highlights the necessity to validate the reprocessing procedure taking the commonly available equipment and methods into consideration.
The manufacturers of the SUDs do not provide reprocessing instructions so all aspects of the reprocessing procedure must be developed, implemented and validated by the reprocessors themselves. The validation of a reprocessing process, especially the cleaning, is a task which can not be performed in a hospital, because the required equipment, knowledge, experience and resources are highly unlikely to be available. Therefore, reprocessing of SUDs in hospitals is considered to be unfeasible in hospitals.

5.4 Washer-disinfectors

Standard washer disinfectors used for cleaning and disinfecting surgical instruments are not designed to deal with the design features of complex medical devices, like long narrow lumen, which are frequently encountered in SUDs. The pressure required might be too high. Frequently, there are no connectors available to connect the devices to the washer-disinfector. Most standard washers use thermal disinfection (temperatures up to 93ºC), which is unsuitable for thermolabile devices.
Another factor to consider is the compatibility between the detergents and other chemicals used in the washer disinfector. The chemistry used shall be compatible with the materials used for the construction of the SUDs. This might require the use of other detergents for cleaning SUDs than the ones commonly used.

5.5 Sterilizers

The most commonly used method for sterilization is steam sterilization. Because most SUDs are thermolabile, steam sterilization has limited use for resterilizing SUDs. The method most frequently used for (re)sterilization of thermolabile devices is ethylene oxide. However, due to the toxic and explosive nature of ethylene oxide, extensive precautions are needed when using ethylene oxide, requiring considerable investments. Over the last two decades, ethylene oxide has disappeared from most hospitals. In the Netherlands for example, there is nowadays no hospital that operates an ethylene oxide sterilizer. This is mainly due to the measures that need to be taken, but also due to the fact that for nearly all RMDs steam sterilizable versions are available. Therefore, the sterilization of SUDs will not be feasible in most hospitals.

5.6 Validation

The tests and checks that shall be performed as a part of the validation procedure shall be determined by risk analyses. At least it should be established that the cleaning procedure removes the contamination to a level sufficient for further reprocessing and subsequent use. This not only concerns the level of organic residues (blood, tissue) but also the residues of process chemicals and pyrogenic substances. Depending on the sterilization process to be used, the bioburden of the device shall be established. The validation shall also include functionality and biocompatibility testing after sterilization and at the end of the device’s shelf life.

As mentioned in paragraph 5.3, most validation activities are not and cannot be undertaken by hospitals.
When reprocessing SUDs, ethylene oxide sterilization is likely to be the preferred method of sterilization. Validating ethylene oxide sterilization also requires special equipment, knowledge and experience, mainly related to microbiological testing and biocompatibility testing. This equipment, knowledge and experience is not commonly available in hospitals nor with validation companies. Moreover, the maximum number of reuses shall be established. This requires the tests and assessments mentioned above to be carried out a number of times, to establish the effect of multiple reprocessing cycles and uses on the device.

5.7 Required information

The following data need to be generated to substantiate the appropriateness of reprocessing processes for SUDs:

- Detailed instructions for cleaning, disinfecting and sterilizing the SUD.
- Validation of the reprocessing process, demonstrating that a functional and safe product is obtained. This includes a demonstration that the material quality and the construction of the medical devices remain acceptable after reprocessing, although not necessarily identical to the original product.
- The maximum allowed number of reprocessing cycles.
- Registration of all critical process parameters during cleaning, disinfection and sterilization of the devices.
- Registration of the tests carried out during reprocessing to establish the safe and/or correct functioning of the device.

6 Legal considerations and responsibilities

6.1 Conclusion

Until now, the main responsibility for using a reprocessed SUD resides with the user of that device. It is unclear what the responsibilities of a third party reprocessor are. To make the responsibilities for reprocessing SUDs clearer, the reprocessor has to be considered to produce a new medical device, requiring assessment by a notified body and affixing the CE-mark.

6.2 Original manufacturer

The OEM designed the SUD for single use on a single patient, after which it is to be discarded; reprocessing is not an issue. Generally, this is clearly communicated to the user of the device. The revised MDD requires the original manufacturer of a SUD to indicate which risks are associated with the reuse of that device and communicate these risks to the user; *§13.6h: If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request.* The user is well informed about the fact that the device is not intended to be reused and the risks that are associated with multiple use. If a user deviates from the intended use of a SUD, and the manufacturer has explicitly stated that the product is for single use only, the OEM can not be held responsible for the safety and functionality of the reused device.

In some regions of the world, the patient bound reuse of some types of SUDs is common practice, e.g. reuse of haemodialysis filters. If this is known to the manufacturer and if this practice is accepted by the medical profession, and if these practices might even be beneficial for the patient because of less biocompatibility problems, the manufacturer should provide the necessary instructions for reuse and indicate the number of reuses[7]. For the Netherlands this is not an issue, haemodialysis filters are not reused.

Another exception could be considered. The packaging of a SUD is sometimes opened by accident e.g. as a result of a miscommunication during an operation or a surgeon choosing an incorrect size of a device by mistake. Strictly following the instructions for use, the device should be discarded. One could argue that, when the packaging is opened and the device is not taken out of the package and not contaminated with patient material, cleaning is not necessary and resterilization only would suffice. For these cases, the OEM should provide repacking and resterilization instructions. It has to be demonstrated that repetitive sterilization does not adversely affect the materials and/or the construction of the device.

6.3 The user

The user is considered to be fully aware that the OEM has no obligation to support the reprocessing and reuse of the SUD. If the user decides to reuse a SUD, it is his responsibility to establish that the product is safe, functional and that it meets the essential requirements of the MDD after reprocessing.

When reprocessing reusable devices, the essential requirements are fulfilled by definition as long as the user precisely follows the reprocessing instructions as provided by the manufacturer, including the prescribed maintenance, tests and checks.

[7] Favero, M.S., Requiem for reuse of single-use devices in US hospitals, *Infection Control and Hospital Epidemiology* 22 (9), pp. 539-541, 2001

6.4 The reprocessor

The reprocessor (irrespective whether the reprocessor is the user or a third party) has to perform the cleaning, disinfection and sterilization process of SUDs according to the established protocols.
The reprocessor has to demonstrate that the reprocessed device is safe to use; the device shall continue to fulfill the essential requirements of the MDD after reprocessing. This is a similar requirement as for the OEM.
In many cases, the reprocessor is also the entity performing the validation of the reprocessing processes. The reprocessor has to be expected to perform the reprocessing process and its validation to the best of his abilities. Under the current legislation the reprocessing of SUDs does not fall under the MDD, as long as the reprocessor does not place a reprocessed device on the market. Basically the reprocessor provides a service to the user. In this situation, it is unclear who is responsible for the safety and quality of the reprocessed product.
For RMDs, it is assumed that the device continues to fulfill the essential requirements as long as the instructions for reprocessing provided by the manufacturer are followed. Therefore, hospitals do not have to perform a battery of tests on the devices, which they are unlikely to be able to perform.

6.5 Status and identification of reprocessed SUDs

To prevent confusion between the original SUD and the reprocessed one, a reprocessed SUD shall be identified in its own right. There shall be no confusion possible between the OEM and the reprocessor. The OEM delivers the SUD for single use. Once it has been used it is no longer a medical device, but it has become waste. Starting from this position, the reprocessor produces a new device, using the discarded used SUD as raw material. The reprocessor shall ensure the renewed device is safe to use; basically that it fulfils the essential requirements of the MDD. As a consequence, the device shall be marked according the requirements in the MDD; that is with the name of the reprocessor and a CE-mark. All markings of the OEM shall be removed as far as possible without jeopardizing the safety and functionality of the device, as the OEM is no longer responsible for this device.
Requiring the reprocessor to treat the reprocessed SUD as a new medical device will in most cases also require the involvement of a notified body.

7 Possible changes to the legislation

7.1 Principles

The following principles were used for proposing changes to the legislation:

- A SUD is not intended to be reprocessed; the device is not CE-marked for reuse.
- The OEM is not responsible for a reprocessed SUD. As far as he is concerned, the SUD is waste material after it has been used. It is only fair that the OEM can not be held accountable for all other uses after this stage.
- Reprocessing a used SUD is de facto manufacturing a new device from waste material.
- It shall be demonstrated that the new device meets the essential requirements of the MDD.
- For RMDs, the prescribed reprocessing procedure shall be validated.

7.2 Proposed changes

To enforce these principles, the reprocessing of SUD should be regulated in the MDD by:

1. Extending the definition of single use device to emphasize that after the SUD is used, it is no longer a medical device, but is converted into medical waste. This is in fact already covered by the definitions of ‘single use device’ and ‘medical device’, but should be emphasized.
   A ‘single use device’ is by definition “intended to be used once only for a single patient”. Therefore, after this single use it is no longer suitable to be used for one or more of the purposes defined in the definition of medical device:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
   - investigation, replacement or modification of the anatomy or of a physiological process,
   - control of conception.

   Since the used SUD is not suitable anymore to be used as a medical device, the used SUD can no longer be considered a medical device.
2. Defining that the entity that is reprocessing discarded SUDs is a manufacturer of medical devices, using medical waste as the raw material.
3. Requiring that as a manufacturer of a medical device, the reprocessor shall follow all obligations in the MDD, including classification of the device, risk analyses and where necessary notified body involvement in the conformity assessment procedures.
4. Requiring that the reprocessed medical device shall be affixed with the CE mark.
5. Requiring that all the markings identifying the OEM, the original brand name, type name or number etc. shall be removed from the device, as long as this does not jeopardize the safety and functionality of the device.
6. Requiring that the reprocessor shall mark the reprocessed device with his own name according to the provisions of the MDD.
7. Requiring that the reprocessor shall not make any reference to the OEM, the original brand name etc.
8. Requiring that the device shall be clearly marked to inform the user that the device has been made from a previously used SUD.

To force manufacturers of RMDs to validate the reprocessing procedures:

1. Reclassify RMDs based on their intended use instead of as Class I using classification rule 6, which classifies reusable surgical devices as Class I.

In national legislation, the following requirement shall be incorporated:

1. All devices used in medical procedures must be medical devices.

7.3 Advantages

This proposed changes have the following advantages:

1. It is fair towards the OEM, and may take away many of Eucomed's objections towards reprocessing of used SUDs.
    a. The OEM has put effort and money in the development, production and CE-marking of the SUD to ensure that a safe product is brought to the market. It is only just that also a reprocessor that converts a used SUD into a new medical device shall also demonstrate that the device is safe for use by demonstrating compliance with the essential requirements of the MDD.
    b. As far as the OEM is concerned, the SUD becomes a waste product after use. If whoever decides that they want to produce from this waste product a new medical device, the OEM should not be at risk of being confronted sooner or later with the consequences of the reuse that he did not endorse in the first place.
2. It provides clarity for the users. The CE mark identifies the device as compliant to the essential requirements of the medical device directive. In this way the reprocessed device has the same legal status as a new device made from virgin materials and the user does not face the risk of unexpected liability in case the device fails. As with any other CE marked medical device the manufacturer is fully responsible for product failure.
3. It takes away the political risk for the government. They do not have to endorse the reuse of SUD through national legislation when reprocessed SUDs are considered equal to all other MD. In this way the Dutch government can not be held accountable for any patient deaths resulting from the reuse of SUDs.
4. This approach is similar (although not identical) to the situation in the United States of America, when the FDA approves the reprocessor reprocessing SUD in the USA.
5. By reclassifying reusable surgical medical devices, most of these devices will be classified in a higher class, which requires an assessment by a notified body. Moreover, reusable devices can not be considered to pose a lower risk than single use devices.

8 Overall conclusions

It is proposed for the reuse of SUDs to redefine used SUDs as waste material. Anyone reprocessing these used SUDs to make them available again for use should be defined as a manufacturer that uses waste material to produce new medical devices. The reprocessor is then defined as a manufacturer and has to comply with all the requirements of the MDD, including CE-marking of the devices, performing risk analyses, notified body involvement, etc. For the user this has the advantage that no matter whether they use a new device from an original manufacturer or a renewed device from the reprocessor, the safety of the device is guaranteed through the CE mark.
Reclassifying reusable medical devices based on their intended use right instead of as class I using classification rule 6, will result in most devices being in a higher risk class. For devices in a higher risk class than class I, a notified body has to be involved in reviewing the design of devices, which forces manufacturers to validate their reprocessing instructions.

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