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Disinfectants for medical devices

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Abstract

Until 1995 all disinfectants available on the Dutch market were registered under the Pesticides Act. With the introduction of the Medical Device Directive in the Dutch law disinfectants specifically intended for use on medical devices are considered as medical devices. These are CE marked by the manufacturer and freely marketed in the EU without the need for national approval. In the Netherlands users of disinfectants are concerned that without the strict registration procedures demanded by the Pesticides Act, manufacturers make unfounded product claims. Therefore, product labels and user's instructions of disinfectants were analysed. From the 85 products, 35 (41%) showed faulty application of the CE mark. This is mainly due to the faulty application of rule 15 of the classification rules in the MDD by manufacturers and notified bodies. The choice of a disinfectant for a certain application has to be made on the claims of the manufacturer. The information provided on the label alone is generally insufficient to make an educated choice. For the safe use of a disinfectant, detailed information about concentration, contact time, (minimum) temperature, microbial species against which the product is active and the field of application need to be clearly stated. Therefore, a standard for the labelling of disinfectants is desired.

Preface

The study described in this report could not have been performed without the kind corporation of the Dutch hospitals, the Dutch suppliers of disinfectants, the European manufacturers of disinfectants and the notified bodies. Special gratitude goes to Mr. E. Kolsteeg from the Dutch Dental Suppliers Association (VGT) for his substantial contribution in the collection of product labels and user's instructions.

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Samenvatting

Tot 1995 werden alle desinfectantia op de Nederlandse markt geregistreerd onder de Bestrijdingsmiddelenwet. Met de introductie van het Besluit medische hulpmiddelen worden desinfectantia die specifiek bedoeld zijn voor de desinfectie van medische hulpmiddelen geclassificeerd als medische hulpmiddelen. Conform de bepalingen in het Besluit worden deze door de fabrikant voorzien van het CE merk en kunnen vrij in de Europese gemeenschap verhandeld worden zonder aanvullende nationale toelatingen. De gebruikers van desinfectantia vrezen dat zonder de strikte eisen uit de Bestrijdingsmiddelenwet de fabrikanten eigenschappen aan hun producten toekennen die ze niet volledig kunnen onderbouwen. Op verzoek van de Inspectie voor de gezondheidszorg (IGZ) heeft het RIVM een onderzoek uitgevoerd. De fabrikanten, ziekenhuizen en de aangemelde instanties werden benaderd voor informatie over het aanbod van desinfectantia op de Nederlandse markt, de gevolgde CE conformiteitsprocedures, het testen van de producten en de informatie op de etiketten van de producten. De informatie is gegroepeerd en geanalyseerd.

Van de 85 producten waarvan de informatie op het etiket is geëvalueerd is op 35 producten (41%) het CE merk ten onrechte aangebracht. Dit is veelal terug te leiden naar de ‘ruime’ interpretatie die door de fabrikanten en aangemelde instanties aan het begrip medisch hulpmiddel wordt gegeven en de daaruit voortvloeiende onterechte toepassing van regel 15 uit de classificatieregels uit het Besluit . Het is aan te bevelen dat de aangemelde instanties als onderdeel van de conformiteitbeoordeling een actievere rol spelen in de evaluatie van de testprotocollen, teneinde de werkzaamheid van het desinfectans te waarborgen.

De gebruikers moeten op basis van de informatie op het etiket beoordelen of het product geschikt is voor de gewenste toepassing, tenzij de gebruiker bereid is om de testvoorschriften en de testresultaten op te vragen bij de fabrikant en deze te bestuderen. De informatie op het etiket is over het algemeen onvoldoende om een verantwoorde keus te kunnen maken. Voor het veilig gebruik van een desinfectans moet concrete informatie over de concentratie, inwerktijd, de (minimale) temperatuur, het microbiologisch spectrum waartegen het middel werkzaam is en de beoogde toepassing op de verpakking vermeld worden. Een standaard voor de informatie op het etiket van desinfectantia is dan ook gewenst.

Summary

Until 1995 all disinfectants available on the Dutch market were registered under the Pesticides Act. With the introduction of the Medical Device Directive (MDD) in the Dutch law disinfectants specifically intended for use on medical devices are classified as medical devices. These are CE marked by the manufacturer and freely marketed in the EU without the need for national approval. In the Netherlands, users of disinfectants are concerned that without the strict registration procedures demanded by the Pesticides Act, manufacturers make unfounded product claims. These concerns were noted by the Dutch Health Care Inspectorate (IGZ). Therefore, manufacturers, hospitals and notified bodies were asked for information about the available disinfectants on the Dutch market, the CE conformity procedures, product testing and the product labels. The information was grouped and analysed.

From the 85 products of which the information on the label is evaluated, 35 products (41%) showed faulty application of the CE mark.This is mainly due to the fact that manufacturers and notified bodies have a broad interpretation of the definition of medical device and consequent faulty application of rule 15 of the classification rules in the MDD. To assure the manufacturer's claim it is recommendable that notified bodies incorporate the evaluation of test protocols in their conformity assessment.

The choice of a disinfectant for a certain application has to be made on the claims of the manufacturer, unless the user is willing to ask for and study the test protocols and test results from the manufacturer. The information provided on the label alone is generally insufficient to make an educated choice. For the safe use of a disinfectant, detailed information about concentration, contact time, (minimum) temperature, microbial species against which the product is active and the field of application need to be clear stated. Therefore, a standard for the labelling of disinfectants is desired.

1. Introduction

After the implementation of the Medical Device Directive (MDD) in the Dutch law, disinfectants for medical devices are no longer registered by the Board for the authorisation of pesticides (College Toelating Bestrijdingsmiddelen; CTB). Until 1995 all disinfectants were registered under the Pesticides Act. Under the new law, disinfectants that are specifically intended to be used on medical devices are considered as medical devices. Thus the requirements of the MDD apply to this group of disinfectants.
The procedure for market approval has therefore changed considerably. The manufacturer of a disinfectant follows the directions given in the MDD to CE mark the product. The evaluation of the product for micro-biocidal efficacy, safety for the user, the risk of residues on the disinfected product and product testing, which was part of the CTB registration procedure, is now performed under the responsibility of the manufacturer of the product. Nowadays, all products that are CE marked can be freely marketed throughout the European Community, without the legal requirement for additional third party certification or product testing. Nevertheless, additional testing may be required by the users of the product. E.g. in Germany users ask for registration of the product by the German Society for Hygiene and Microbiology (DGHM).
In the Netherlands concern was raised by users of disinfectants. They were worried that without the strict registration procedures demanded by the Pesticides Act, manufacturers may make claims they cannot fully substantiate. European standards to test the efficacy of disinfectants for medical devices under simulated use conditions are still unavailable. Therefore, manufactures have to select tests from national standards and guidelines or even develop their own test methods.
With the change of the admittance procedure, the Dutch Health Care Inspectorate (IGZ) felt the need to gain an insight in the new evaluation procedures of disinfectants. The following questions were raised by IGZ:

- Which annex is used to claim conformity with the MDD?
- Are disinfectants rightfully CE marked?
- Which conformity assessment procedures do the notified bodies use as part of the certification?
- Do different notified bodies apply similar procedures ?
- Is the product information given on the product label and in the manual sufficient for the user to make a valid decision whether to use the disinfectant for a certain application?

2. Methods

2.1 General

The study was performed in three phases.

Phase A
- Identification of the suppliers of disinfectants with CE mark.
- Request to the suppliers for product information.

Phase B
- Evaluation of the information provided on the label and/or manual of the disinfectants with the Essential Requirements in the MDD.
- Evaluation whether the CE mark has been applied rightfully.
- Identification of the notified bodies that were involved in the CE conformity procedure followed by the manufacturer.
- Identification of the procedures followed by the Notified Bodies in the assessment of the CE conformity procedures followed by the manufacturer.

Phase C
- Identification of the test procedures followed by the manufacturer to establish the efficacy of the disinfectant.
- Establish whether the tests that are performed by the manufacturer are sufficient to substantiate the claims of the manufacturer.

2.2 Phase A

2.2.1 Identification of the potential suppliers of disinfectants with CE mark

From the following sources, a list of the potential suppliers of disinfectants on the Dutch market was made.
- The authors' knowledge of suppliers' assortment.
- The internet.
- Suppliers' catalogues.
- The yearbook of the Dutch Federation of Technology Branches (FHI).
- The Dutch Dental Suppliers Association (VGT).

In addition, 110 hospitals were asked to identify the disinfectants that were used for the disinfection of medical devices.

2.2.2 Request to the suppliers for product information

The suppliers identified were requested to name all the CE marked disinfectants they sold at the time in the Netherlands and they were asked to provide the RIVM with copies of the product labels and the manuals.

2.3 Phase B

2.3.1 Evaluation of the accompanying information

From the requirements in the MDD a checklist was 'distilled' and guidance to the interpretation of the requirements was added (see appendix 1). The interpretation given by the authors is not necessarily in line with the original ideas of the European Commission at the time the directive was written. Although the medical device directive provides requirements for labels on medical devices, specific requirements for the information on the labels and in the manuals of disinfectants are not given. The requirements for the information provided on labels and in manuals are given in several sections of the directive. Some requirements are repeated in different sections, but are not always identical. The labels and manuals were evaluated using the checklist.

2.3.2 Evaluation whether the CE mark has been applied rightfully

The MDD states in the classification rules (annex IX, chapter III clause 4.3) that 'all devices intended specifically to be used for disinfecting medical devices are in Class IIa'. Thus, a disinfectant is a medical device when:

- It is only to be used for the disinfection of medical devices.
- It is not to be used for the disinfection of any other item.

The CE mark shall only be applied when the product is a medical device. Disinfectants that have a broader application by explicit or implicit claim by the manufacturer are not medical devices and should therefore not be CE marked.

Checks were made whether the products were classified correctly, according to the above mentioned rule.

2.3.3 Identification of the notified bodies

The notified body that was involved in the CE procedure is identified by the number that is printed with the CE mark. A list of the notified bodies and addresses was found on the internet at http://www.dimdi.de/de/mpg/adress/nb-list.htm.

2.3.4 Identification of the conformity assessment procedures

A request was sent by IGZ to the notified bodies to name:

- The annex of the medical device directive that was used in the conformity assessment procedure for the disinfectants baring the CE mark number of that particular notified body.
- The names and numbers of the international, European or national product/test standards that were applied in the conformity assessment procedures for each of the products in the list.

The request was sent to thirteen notified bodies, seven in Germany, four in Great Britain, one in France and one in Austria. The addresses of the notified bodies were found on the internet at http://www.dimdi.de/de/mpg/adress/nb-list.htm.

2.4 Phase C

2.4.1 Identification of the product test procedures

From the list of disinfectants (appendix 2) twenty products were chosen at random. From this group, the products not bearing the CE mark or of which no label or manual was received, were removed. From the remaining products only one per brand was allowed in the list. The first ten products that fulfilled these criteria were put on the final list.
The IGZ wrote a letter to the manufacturers of the selected products requesting the test procedures which were used to substantiate the manufacturer's claims.

2.4.2 Evaluation of product test procedures

The information received from the manufacturer was evaluated to make a list of the European or national standards that have been followed and to check whether these standards are applicable for the specific product. Where national guidelines were followed, RIVM asked for an expert's advise whether these guidelines were acceptable.

3. Observations and results

3.1 Phase A

3.1.1 Identification of the potential suppliers of disinfectants with CE mark

From the information that was available from the various sources a list of 125 possible suppliers was assembled.
From the 110 hospitals that were requested for a list of the disinfectants used in the hospital for the disinfection of medical devices, about half of the hospitals (61) responded to the request. The hospitals named 82 products, including 30 detergents or maintenance products. Of the disinfectants four were intended for skin disinfection, five were alcohol in water solutions. Domestic chlorine bleach was mentioned three times. Under the current legislation the products for skin disinfection are registered as medicinal products, the alcohol in water solutions were historically exempt from the registration under the Pesticides Act. Domestic chlorine bleach is registered under the Pesticides Act by the CTB for other applications than the disinfection of medical devices. The remaining products were also identified by the suppliers (see 3.1.2).

3.1.2 Request to the suppliers for product information

From the 125 potential suppliers, initially 87 suppliers responded, including the members of VGT. VGT responded on behalf of it's members and sent a list of the disinfectants sold by the member companies as well as the requested documentation. From the 38 companies that initially not responded, 11 companies were contacted by telephone which led to 7 more responses. In total 75% of the addressed companies responded. From the collected information a list of 104 different products was composed.

From the list of 104 products 19 products were deleted. For ten products, no labels were provided or the labels were illegible. For two of these ten only a manual was provided. Two products were identified as a skin disinfectant, five products were registered under the Pesticides Act and two products were identified as 80% ethanol in water solutions.Of the remaining 85 products, 80 were CE marked including the identification number of a notified body. See appendix 2 for the list of these 80 CE marked disinfectants, sorted per notified body.

3.2 Phase B

3.2.1 Evaluation of the accompanying information

The results of the evaluation of the labels and the manuals of the 85 products are summarised below in the three major groups

3.2.1.1 Instruction for use

In general (83%) the manufacture's instructions gave information on the concentration, minimum exposure time and where applicable the temperature. Although the activity of all disinfectants is temperature depended by nature, none of the manufacturers stated a minimum temperature. The necessary exposure times for some products (alcohols) may be unrealistic high, taking the volatility of the product into consideration.

No attention was drawn to the risks related with residues of the disinfectant on the disinfected medical devices. In 45% of the examined products instructions were given for the post disinfection treatment. For 30% of the products no post disinfection treatment was necessary because the product leaves no residues or the disinfected objects are put through a washing process afterwards. For quite a large number of products (25%) no instructions for the post disinfection treatment were given. Where rinsing with water was prescribed, no specification for the quality, temperature and amount of the rinse water were given. Only for disinfectants for dialysis machines guidance was given to establish the efficacy of the post disinfection rinse. Contrary, with products for the disinfection of dental burrs the manufacturers gave the explicit instruction not to rinse the device after disinfection. This to prevent an adverse reaction (i.c. corrosion) between the material of the device and the disinfectant solution. The maximum period of use after the disinfectant has been diluted or activated is limited by time alone (e.g. the solution may be used for a period of 14 days). No manufacturer stated a maximum number of reuses, although the suitability of the solution is limited by evaporation of the actives, dilution with adhering rinse water or contamination from poorly cleaned medical devices. Means to check the concentration of the active ingredients were only offered with two products, both from the same manufacturer. The expiry date and batch number were not printed on the label in 48% of the cases. It is unclear whether these data were omitted or that they were printed on the disinfectant container itself.

3.2.1.2 Anti microbial spectrum

For 88% of the products the manufacturers gave an indication of the anti microbial spectrum in broad terms; bactericidal, virucidal and/or fungicidal properties. For 75% of the products activity against HBV and HIV was claimed and action against tuberculoses was mentioned for 24% of the products. According to the information on the label 33% of the products were listed by the DGHM. Compliance with the AFNOR standards was stated for 18% of the products.
Virucidi is not tested in a direct manner. The Morphological Alteration and Disintegration Test (MADT) is mentioned on 12% of the products, the Hepatitis B surface antigen test (HBsAg) also on 12% of products. Reference to the German Association against Virus Diseases (DVV) was made on 3% of the labels.
There is, however, some concern about the claims made by the manufacturers. The inactivation of viruses by quaternary ammonium compounds (quads) is not beyond doubt. A quad is not a univocal compound. The composition of the four ‘tails’ of the molecule can be varied in many ways, all influencing the biocidal properties of the product. Although quads may have virucidal properties this is not necessarily the case for every quad.
For some alcohol mixtures intended for surface disinfection the biocidal properties were claimed for an exposure time of 15 minutes. Given the volatility of the liquid, it is unlikely that 15 minutes exposure is feasible on an open surface.

3.2.1.3 Safety

Much information was provided about the safe use and storage of the product (79% of the labels), but always focussed on the safety of the person handling the product or other persons (e.g. keep away from children). No information was given about the safety of the patient. The so-called R (Risk) and S (Safety) sentences that should be printed on the label (Law on hazardous substances; 67/548/EEC) were omitted on 64% of the products. In 5 cases (6%) the warning symbols were missing.

3.2.2 Evaluation whether the CE mark has been applied rightfully

From the 85 products of which the information on the label was evaluated, on 35 products (41%) the CE mark was not applied rightfully. In these cases the application of the product as recommended by the manufacturer was wider than only the disinfection of medical devices, e.g. medical instruments and table tops. For some products the intended application was somewhat vague, e.g. the surfaces of medical equipment or medical objects. Rule 15 of the classification criteria does not apply to these disinfectants. These particular products were mainly alcohol sprays, wipes or pads impregnated with an alcohol based solution. For a number of products it was uncertain whether the items that were intended to be disinfected with the particular product were medical devices, eg therapeutic baths, dental imprints that are used as a mould for dental prosthesis or cooling water for dental drills (see also appendix 3).

One product did not bear the CE mark, where it should. It was a disinfecting solution to be used in combination with pumice stone powder as a polishing paste for teeth. The polishing paste is a medical device, therefore this particular disinfectant was a medical device (see also appendix 4).

Two products were CE marked ,but were wrongly classified as class I. One product was a dedicated detergent to be used in a particular instrument washer. The manufacture claimed anti-microbial action of the product, therewith positioning the product as a disinfectant. The intended use of the other product was not limited to the disinfection of medical devices and should not be CE marked at all (see also appendix 4).

One product did not bear the CE mark and it was unclear whether this is wrongful or not. The disinfectant was a chlorine solution and had a wide range of applications. Therefore, it was not a medical device and should not bear the CE mark. The manual of a therapeutic bath specified this particular disinfectant for the disinfection of the bath. The disinfectant could therefore be considered an accessory to the bath. In that case the disinfectant should bear the CE mark (see also appendix 4).

3.2.3 Identification of the notified bodies

Thirteen notified bodies were identified by the number on the product label (see appendix 2).

3.2.4 Identification the conformity assessment procedures

From the thirteen notified bodies that were addressed, nine (69%) responded to the request for information. Seven notified bodies indicated that annex II (EC declaration of conformity; full quality assurance system) of the medical device directive was used. One of these seven indicated that annex V (EC declaration of conformity; production quality assurance) was used for a product that is originally manufactured by another manufacturer than the manufacturer named on the label; the so-called original equipment manufacturer (OEM). One notified body only mentioned the use of annex V. However, the use of annex V is only allowed when this is done to complement the procedure described in annex VII. One notified body mentioned annex VII in combination with annex V.

Table 1. CE conformation procedure as identified by the Notified Bodies.

Notified Body, country	Annex of MDD, conformity assessment procedure	Product standards used	Identification of used product standards
1. Germany	II	-	
2. Germany	II	-	
3. Germany	II	+	Guidelines of DGHM
4. Germany	II V in case OEM products	-	
5. Germany	VII in connection with V	+	Guidelines of DGHM.
6. Germany	*No reaction received*		
7. Germany	*No reaction received*		
8. United Kingdom	II	+	AOAC methods, TGO 54 NF T 72-201, NF T 72-231, NF T 72-151, NF T 72-171, NF T 72-180
9. United Kingdom	II	-	
10. United Kingdom	II	-	
11. United Kingdom	V	-	
12. Austria	*No reaction received*		
13. France	*No reaction received*		

The notified bodies indicated that they were not involved in the product testing or the evaluation of the test results. For test procedures and test reports the notified bodies refer to the manufacturers of the product. One notified body attached the declaration of conformity from the manufacturer. This manufacturer stated that the product is tested by third parties and conforms to the guidelines of the DGHM.

3.3 Phase C

3.3.1 Identification of the product test procedures

From the ten manufacturers that were addressed for information about the test procedures for the specified products, eight responded. The two non-responders were in fact one manufacturer who was addressed twice, for two products that are marketed under different brand names. One manufacturer refused to submit the requested information. The manufacturer ‘advised’ us to contact his competent authority whenever there is doubt on the quality of his products. In total five of the responding manufacturers specified the test procedures.

The manufactures indicated that the CE conformity procedure annex II or V is used. In the MDD annex V is only given as an option for class IIa devices when used in combination with annex VII. Two manufacturers sent a copy of the certificate of the quality assurance system assessment as well as a list of the products that were manufactured under this quality assurance system. These lists contained disinfectants that were not specifically used for the

disinfection of medical devices. These products are not medical devices and should not be CE marked.
See appendix 5 for more information on the response from the manufacturers.

3.3.2 Evaluation of the product test procedures

Four out of the five manufacturers tested their products to the national standards and guidelines. Three German manufactures had their products tested by third parties to the guidelines from the DGHM. One of these manufacturers 'complained' that to his observation, there does not seem to be a unique DGHM guideline. This manufacturer also stated that recent tests were successfully performed by a third party to prEN13727[1]. One Swiss manufacturer named, besides the guidelines of the DGHM, the guidelines from the DVV / Bundes-gesundheitsamt (BAG) and the AFNOR/European standards. The fifth manufacturer gave a detailed list of the tests that have been performed by seven independent bodies and four studies by the manufacturer's laboratory. In absence of European standards the manufacturer used 'national standards'. The manufacturer did not specify these standards, but they were identified by the notified body as the DGHM guidelines.

One manufacturer stated that the disinfecting wipes are effective with a contact time of 2 minutes. A contact time of 2 minutes is hard to realise with a wipe. Practice is that wipes are used to wipe surfaces, where the contact time between the surface and the wipe is in the range of seconds. The liquid that remains on the surface after wiping has a high alcohol content and is likely to evaporate swiftly. The information in the DGHM list of March 2000 states that for wipes the disinfecting solution is tested, rather than the finished product. Thus the wiping process is not taken into account.

[1] Preliminary publication of the European standard; Chemical disinfectants; Quantitative suspension test for evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area; Test method and requirements (Phase 2/Step 1)

4. Discussion

General

- The response from manufacturers, hospitals and notified bodies to the requests from the RIVM and the IGZ was rather disappointing. Especially with regard to the request for the test procedures from IGZ to the manufacturers we have expected a swift response. For only five of the ten selected products the test method was received. The same holds true for the response of the notified bodies to the requests from IGZ. We would have expected a timely and accurate response to the requests from a national competent authority.
- The admittance of disinfectants on the Dutch market is regulated in two laws. The disinfectants for medical devices are admitted under the Medical Device Directive. All other disinfectants are admitted under the Pesticides Act, which will be amended according the Biocide Directive in due time. There is no registration of disinfectants that fulfil the requirements of the MDD. All disinfectants that are admitted under the Pesticides Act are registered and the information about the active ingredients, instructions for use and the field of application are evaluated by an independent committee. For disinfectants with a CE mark users have to rely on the information provided by the manufacturer.

Instructions for use

- The quality of the information on the label of the product varies. Manufacturers are sometimes vague in stating the field of application. E.g. it is presented as a broad application on medical items, not necessarily medical devices. The CE mark is applied unjustly in these cases. For nearly all products the anti-microbial spectrum is indicated in broad terms; the manufacturer is claiming bactericidal, virucidal and/or fungicidal properties. The claimed effectivity is not beyond doubt for a number of products e.g. the inactivation of viruses by quaternary ammonium compounds.
- In general the manufacturer's instructions are clear for the concentration, minimum exposure time and, where applicable, the temperature. None of the manufacturers state a minimum temperature. The necessary exposure times for some products may be unrealistic high. Given the volatility of alcohol solutions/mixtures, it is unlikely that prolonged exposure (in the order of minutes) is feasible on an open surface. The risks related with residues of the disinfectant on the disinfected medical devices are not given. The maximum period of use is limited by time alone (e.g. the solution may be used for a period of 14 days). No manufacturer states the number of reuses (e.g. not to be used more than 10 times). Only one manufacturer offers a method to check the concentration of the active ingredients.

Notified bodies

- The notified bodies that are consulted for the CE conformity procedures were easily identified by the identification number printed with the CE mark.
- The involvement of the notified bodies in the CE procedure is limited to the evaluation of the quality control system according annex II. Alternatively annex VII in combination with annex V is used. The application of only Annex V is also mentioned, although it is not an option given in the MDD. Notified bodies typically do not perform product tests or evaluation of the product tests carried out by the manufacturers or third parties.

Product testing

- The product evaluation by the manufacturers is mainly based on test procedures given in national guidelines. The European standards are followed by only a few manufacturers.
- Based on the information on the labels, 33% of the products fulfil the requirements of the DGHM. The use of the European standards and the DGHM guidelines is acceptable. Products fulfilling these requirements are deemed to give the desired bactericidal effect. However, users of disinfectants must be aware that a particular field of application may require particular action of the disinfectant on specific micro-organisms, e.g. mycobacteria, viruses, yeasts and fungi.
- More relevant European methods for product testing on simulated medical devices are still under development. The test methods in the published European standards and the methods recommended by the DGHM are so called suspension tests. The results from these test do not necessarily correspond with the results from simulated use tests.

5. Conclusions and recommendations

The choice for a disinfectant for a certain application has to be based on the claims of the manufacturer, unless the user is willing to ask for and study the test protocols and test results from the manufacturer. Independent verification of the product is not necessarily provided by the current legislation, but on a national level, professional associations may provide third party evaluation of disinfectants, e.g. the DGHM in Germany.
With the availability of European standards for disinfectants, the product tests and the information on the label are likely to become standardised in time. This is especially the case when the standards are supported by professional associations for microbiology, hygiene and infection prevention.
All the important information for the user should be printed on the label. The MDD does, however, not give sufficient detail about the required information to be printed on the labels of disinfectants. For the effective use of a disinfectant information about concentration, contact time, (minimum) temperature, microbial species against which the product is active and the field of application need to be absolutely clear. A standard for the label of a disinfectant is desired. Imperfections in the provided information on the labels of medical devices are not unique for disinfectants. A recent Dutch study about Class I medical devices showed flaws in all the label and/or instructions for use (RIVM report 318902010, 2003). Initiatives for the standardisation of the label are taken by CEN TC216[2] and the Organisation for Economic Cooperation and Development (OECD). Under the Pesticides act, registration of a disinfectant was only possible if the product was able to pass the standard suspension test and the information on the label was sufficiently detailed. The instructions on the label had to be evaluated, and by proper labelling this lead to registration of the product in clear relation with the claims of the manufacturer and the field of application. Under the MDD the quality of the product and the label is the sole responsibility of the manufacturer. It is under these circumstances possible that the label may not provide all the necessary information. Professional users, like hygienists and micro-biologists, are able to obtain more information or advise from professional associations to judge whether a particular disinfectant is suitable for the job. However, users with less knowledge of hygiene or micro biology, like dentists, general practitioners and paramedics, may not have access to more detailed information and may lack the knowledge to make an educated decision. Especially, for the latter group a clear and detailed label is necessary.

Disinfectants should be provided with means to check the correct function of the product, to test the concentration before first use and in case of re-use of the disinfectant, to establish the number of re-uses. Only one manufacturer provides test strips to indicate the concentration of the active ingredient in his products.

Testing of products by the manufacturer is not unacceptable, provided that recognised and validated test procedures are used. German manufacturers make clear reference to the guidelines of the DGHM. The question remains whether all manufacturers are using reliable, validated test methods. The standards or guidelines used for the testing of the product should be stated on the label so that the user can determine the suitability of the product for its propose.

[2] Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics.

There is a lack of relevant harmonised (European) standards. The development of the European standards is being worked on, but progress is slow. Standards should become available as soon as possible and be adapted by the national organisations involved in the testing and registration of disinfectants.

The study indicates inappropriate use of the CE mark. Manufacturers tend to be vague about the intended use of the product or to stretch the definition of medical device so that materials and objects used in the doctor's practise are considered medical devices. It is recommendable that notified bodies are consulted for the interpretation of the definition for medical device and for the classification procedure to be followed.

The CE conformity procedure based on Annex II alone, does not provide the same level of assurance that the manufacture's claims are valid as does independent testing or alternatively, evaluation of the test protocols of the manufacturer. It would be recommendable that notified bodies would incorporate the evaluation of test protocols in their conformity assessment.

Appendix 1 Checklist for the information provided with CE marked disinfectants

(The text printed in *italics* give the interpretation of the authors of the particular requirement in the MDD).

MDD essential requirements [er] 13.1 "Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use."

Checklist labels of CE marked disinfectants

1. CE mark including the identification number of the notified body responsible for the implementation of the procedures set out in Annexes II, IV, V and VI.
   (MDD art. 17.)
2. Information necessary for safe use of the product.
   (MDD er 13.1)
   - *safety precautions (e.g. ventilation of work area)*
   - *personal protection (e.g. clothing, gloves, glasses)*
   - *combination with other substances (e.g. compatibility with detergents and medical instruments/devices)*
3. Warnings and/or precautions to take
   (MDD er 13.3.k)
4. The name or trade name and address of the manufacturer.
   (MDD er 13.3.a)
   - *name and address in the EU*
5. The details strictly necessary for the user to identify the device and the contents of the packaging.
   (MDD er 13.3.b)
   - *name of the product, designation that the product is a chemical disinfectant, chemical composition (main compounds and concentration)*
6. Batch code or the serial number.
   (MDD er 13.3.d)
7. Expiry date.
   (MDD er 13.3.e)
8. Where appropriate, an indication that the device is for single use.
   (MDD er 13.3.f)
   - *intrinsic with impregnated pads, wipes and sprays*
9. Any special storage and/or handling conditions.
   (MDD er 13.3.i)
   - *with wipes and pads the instruction to close the container*
   - *in general, keep away from children*
10. Any special operation instructions.
    (MDD er 13.3.j)
    - *necessary preparation of the product (e.g. dilution with water or addition of an activator*
    - *instructions for use (e.g. concentration, contact time, temperature or the identification of any 'dedicated' application of the product, like washer disinfectors)*

- *types of micro-organisms which are deactivated by the product with special attention for viruses and mycobacteria*
- *identification of the medical devices that can be disinfected with the product*
- *necessary pre-treatment of the medical devices that are to be disinfected with the product*
- *necessary post-treatment (rinsing) of the disinfected medical devices*
- *maximum period of use of the product when it is prepared for its intended use*

11. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and the instructions for use.
    (MDD er 13.4.)
    At least the following information should be provided:
    - *identification of the product as an chemical disinfectant and the purpose of the disinfectant*
    - t*he medical devices intended to be disinfected with the product*
    - *types of micro-organisms which are deactivated by the product.*
12. Has the CE marked been applied rightfully?
    Is the product a medical device as defined by Rule 15 of the Classification Criteria? Disinfectants for which the application as specified on the label or in the manual is not limited to medical devices (e.g. table tops, surfaces in the working area, objects in the medical field that are not medical devices and shall not bear the CE mark).

Checklist manual provided with CE marked disinfectant

13. A manual is not necessary when the product can be safely used without a manual.
    (MDD er 13.1, 13.4.)
    A manual is not necessary when:
    - *the product is for dedicated use (e.g. a particular type of washer disinfector or dialysis machine)*
    - *the information that is necessary for the safe use of the product is given on the label*
14. CE mark including the identification number of the notified body.
    (MDD art. 17.)
15. The name or trade name and address of the manufacturer.
    (MDD er 13.6.a)
    - *name and address in the EU.*
16. Identification of the contents of the container.
    (MDD er 13.6.a)
    - *name of the product, designation that the product is a chemical disinfectant, chemical composition (main compounds and concentration)*
17. Where appropriate, an indication that the device is for single use.
    (MDD er 13.6.a)
18. Any special storage and/or handling conditions.
    (MDD er 13.6.a)
19. Warnings and/or precautions to take
    (MDD er 13.6.a)
20. Performance of the product as claimed by the manufacturer and undesirable side-effects (MDD er 13.6.b).
21. If the device must he installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
    (MDD er 13.6.c)

Identification of the equipment in which the product is to be used (e.g. washer disinfector for flexible endoscopes), or a specification of the medical devices for which the product is intended (e.g. dialysis machine).

22. All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times.
    (MDD er 13.6.d)
    - *when the product is put into use, after activation of the product or with products that have a limited period of use, the concentration of the active compounds should be checked (e.g. with an indicator strip)*
23. Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment.
    (MDD er 13.6.f)
    - *the risks of the presence of residues of the product on disinfected medical devices, deterioration of the medical devices on which the product is used and/or material compatibility should be identified*
24. Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.)
    (BMH er 13.6.i)
    - *addition of an activator to the product*
    - *dilution of the concentrate*

Additional requirements regarding hazards accompanying the product.

25. Hazardous products shall be marked with particular warnings in written form (so called R and S sentence and symbols). The rules regarding these markings are complex and the evaluation of hazards for the user in relation to the products was outside the scope of this study.
    However, chemical disinfectants are hazardous products by nature. The user shall be informed by the information on the label about the poisonous and/or inflammable nature of the product and the necessary precautions to take.

Appendix 2 List of products bearing CE mark

Brand name	***Manufacturer*/Supplier in the Netherlands**	**Number of the notified body**
Stammophen	*Dr. H. Stamm GmbH,* *Heinrichstr. 3-4,* *12207 Berlin* *Duitsland* Dr. H. Stamm bv	124
Stammopur 23	Dr. H. Stamm bv	124
Stammopur 24	Dr. H. Stamm bv	124
Stammopur DB	Dr. H. Stamm bv	124
Stammopur DR	Dr. H. Stamm bv	124
Stammopur DR2	Dr. H. Stamm bv	124
Stammopur DR8	Dr. H. Stamm bv	124
FD 322	*OROCHEMIE Dürr + Pflug GmbH + Co. KG,* *Max-Planck Str. 27,* *D-70806 Kornwestheim* *Duitsland* Dürr Dental Nederland	124
FD 333	Dürr Dental Nederland	124
FD 350	Dürr Dental Nederland	124
FD520	Dürr Dental Nederland	124
ID 212	Dürr Dental Nederland	124
ID 212 Forte	Dürr Dental Nederland	124
ID 220	Dürr Dental Nederland	124
Orotol Plus	Dürr Dental Nederland	124
Vector	Dürr Dental Nederland	124
Omniwipes	*Omnident* Dental Union BV	124
Belimed	*Belimed AG,* *Dorfstrasse 4, CH-6275* *Ballwil,* *Zwitserland.* Pentax Benelux B.V.	44
Cidex 14 dagen oplossing	*Johnson & Johnson Medical Limited,* *Gargrave,* *Skipton,* *BD23 3RX,* *Groot Brittanië* J & J Medical B.V.	86

Steris 20	*HOSPITHERA sa,* *Rue E. Féron 70,* *B-1060 Brussel,* *Belgie. (?)* Steris Nederland	86
Ecoster	*Hospal Industry,* *69330 Meyzieu,* *Frankrijk* Hospal BV	86
Turbocidol	*Oro Clean Chemie AG,* *Allmendstrasse 21,* *CH-8320 Fehraltorf,* *Zwitserland* A.D. Jansen Zwolle bv	120
Aseptoprint Rapid	Oro Clean Chemie	120
Dentiro Light	Oro Clean Chemie	120
Dentiro Mikro	Oro Clean Chemie	120
Dentiro Schuim	Oro Clean Chemie	120
Dentiro Sensitive	Oro Clean Chemie	120
Dentiro Wipes	Oro Clean Chemie	120
OroCid Multisept Plus	Oro Clean Chemie	120
OroClean Plus	Oro Clean Chemie	120
OroClean Ultra	Oro Clean Chemie	120
OroLin Borenbad	Oro Clean Chemie	120
Minutenspray	*Alpro Dental Producte GmbH,* *Mooswiesenstr. 9,* *78112 St. Georgen,* *Duitsland* Alpro	123
Minutenwipes,	Alpro	123
Alpron	Alpro	123
Alpron Mint	Alpro	123
BIB forte,	Alpro	123
Diasteril	*Fresenius Kabi Deutschland GmbH,* *Else-Kröner-Str. 1,* *61346 Bad Homburg vd H,* *Duitsland*	123
Micro-10+	*UNIDENT S.A.,* *34 Avenue Eugène-Pittard,* *CH-1206 Genève,* *Zwitserland* Unident	123
Unisepta liquid	Unident	123

Neodisher Drill	*Chemische Fabrik Dr. Weigert (GmbH & Co), Mühlenhagen 85, D-20539 Hamburg, Duitsland* Meko Holland B.V.	297
Neodisher Septo DN	Meko Holland B.V.	297
Neodisher Septo DN2	Meko Holland B.V.	297
Neodisher Septo SF	Meko Holland B.V.	297
Dentavon	*Schülke & Mayer GmbH, D-22840 Norderstedt, Duitsland* Schülke&Mayr Benelux	297
Gigasept	Schülke&Mayr Benelux	297
Lysetol Med	Schülke&Mayr Benelux	297
Mikrozid Tissues	Schülke&Mayr Benelux	297
S&M matic	Schülke&Mayr Benelux	297
Terralin	Schülke&Mayr Benelux	297
Thermosept ED	Schülke&Mayr Benelux	297
Mikrozid Liquid	Schülke&Mayr Benelux,	297
Sekudrill	*Henkel-Ecolab GmbH & Co OHG, P.O. 130406, D-40554 Düsseldorf, Duitsland* HenkelEcolab BV	301
Sekumatic FD	HenkelEcolab BV	301
Sekusept Forte	HenkelEcolab BV, Maxxim	301
Sekusept Plus	HenkelEcolab BV, Maxxim	301
Sekusept Poeder	HenkelEcolab BV, Maxxim	301
Peresal	HenkelEcolab BV, Maxxim	301
Olympus ETD Desinfectans	Olympus, Maxxim	301
Calbenium	*AIREL, 917 rue Marcel PAUL, 94100 CHAMPIGNY, Frankrijk* Airel	433
Dentasept 3H,	*Anios Laboratoires, Pavé du Moulin, 59260 Lille-Hellemmes,* Frankrijk Anios Laboratoires	459
Dentasept PE,	Anios Laboratoires	459
Dentasept ph7	Anios Laboratoires	459

Dentasept Sol et Surfaces	Anios Laboratoires	459
Dentasept Special rotatif	Anios Laboratoires	459
Dentasept spray 41	Anios Laboratoires	459
Dentasept ultra	Anios Laboratoires	459
Lingets	Anios Laboratoires	459
Dialox	*SEPPIC,* *Société du Groupe AIR LIQUIDE,* *75 Quai dÓrsay,* *75321 Paris Cedex 07,* *Frankrijk* Seppic	459
EuroSept Bur	*Henry Schein UK Holdings Ltd., Southall, Middlesex, UB 4AU, Groot Brittannië.* Henry Schein bv.	473
EuroSept Evac liquid	Henry Schein bv.	473
EuroSept Evac powder	Henry Schein bv.	473
EuroSept Impressions	Henry Schein bv.	473
EuroSept Instrument	Henry Schein bv.	473
EuroSept Surface	Henry Schein bv.	473
EuroSept Wipes	Henry Schein bv.	473
Drill Activ	A+D	481
Sugo Activ	A+D	481
Top Activ	A+D	481
Hygiëne tucher	*Dental Central GmbH,* *Carl-Zeiss-Str. 2,* *D-22946 Trittau,* *Germany* Dental Central	482

Appendix 3 Products that are wrongfully CE marked

Product	Intended purpose, which excludes the product from classification rule 15
1	For the disinfection of respiratory masks for personal protection (not medical devices).
2	For the disinfection of respiratory masks for personal protection and laboratory glassware (not medical devices)
3	For the disinfection of dental imprints and imprint spoons (not medical devices)
4	For the disinfection and cleaning of the surfaces of medical devices such as dental hand pieces. (intended use is not precise)
5	Disinfecting powder for dental imprints (not medical devices) and orthodontic equipment.
6	Disinfectant for fast disinfection of small surfaces, medical instruments, medical equipment and the working area (mentioned 3 times).
7	Recommended for the careful disinfection and maintenance of medical equipment with sensitive surfaces and dental chairs.
8	Disinfecting wipes for small surfaces, medical instruments, medical equipment and surfaces.
9	Disinfecting wipes for the disinfection of surfaces of medical devices such as dental handpieces, handles of equipment and general furniture (not medical devices) (mentioned 2 times).
10	Concentrated disinfectant for the continues disinfection of water (not a medical device) and waterlines in dental units (mentioned 2 times).
11	Fast acting disinfectant to be sprayed on the inventory of the doctor's office such as furniture, equipment and accessories (not medical devices).
12	Water disinfectant with prolonged action (not a medical device).
13	Cleaner/disinfectant for surgical instruments and laboratory equipment (not medical devices).
14	Disinfection of prosthesis material and dental imprints (not medical devices).
15	Disinfecting wipes for medical devices and equipment (not medical devices).
16	Surface disinfection of medical products (not medical devices).
17	Fast acting alcohol based disinfectant for medical devices and equipment (not medical devices).
18	Liquid disinfectant for washer disinfectants in the medical and laboratory application (not medical devices).
19	Surface disinfection in hospitals and general practises (not medical devices).
20	For the disinfection of medical linen; further application for domestic linen and towels is indicated with symbols (not medical devices).
21	For the disinfection of medical devices. Suitable for wettable surfaces (not medical devices) (mentioned 2 times).
22	Fast acting disinfectant spray for the medical inventory as per MDD. Also suitable for other alcohol compatible surfaces (not medical devices).
23	Active water purification compound and water softener (not a medical device).
24	Fast and thorough cleaning and disinfecting of floors, medical devices, walls

	and other surfaces (not medical devices).
25	Fast disinfection by spraying on surfaces, medical devices, units and tables (not medical devices).
26	Special cleaner (in the French, German, English end Spanish manual the product is called a disinfectant) for alginates and silicon dental imprints (not medical devices).
27	Very effective cleaner for the fast disinfection of instruments, medical equipment and other surfaces not medical devices).
28	The wrapping of the refill gives no indication of the application (no clear intention for medical devices).
29	For the disinfection of the surfaces of medical equipment (not medical devices). Especially for dental handpieces.
30	Hygienic tissues for general and dental practises (not medical devices).

Appendix 4 Incorrectly classified or incorrectly marked disinfectants

Product a
Disinfecting liquid to be mixed with pumice powder, which as a mixture is used as a polishing paste by dentists. The product is an accessory to the medical device and should be CE marked.

Product b
A disinfectant with a general application, registered under the Pesticides act. The product is specifically prescribed by the manufacturer of therapeutic baths for the cleaning and disinfection. The disinfectant is marketed under the name of the manufacturer of the baths. The baths are provided with a compartment designed for the reception of the disinfectant container and are provided with an automatic dosing system. In this particular case the disinfectant is an accessory to a medical device (the therapeutic bath) and should therefore be considered as an medical device and consequently be CE marked.

Product c
The claim of the manufacturer is not unambiguous. The product is sold as a dedicated detergent to be used in a washing machine for medical devices. On the label the manufacturer claims that the product has 'anti microbial properties', thus implicating that the product is a disinfectant as well. The product is CE marked as a class I device; without the identification number of a notified body. Because of the additional claim of the manufacturer the product should be classified as a class IIa medical device.

Product d
This product is intended for the cleaning of dental suction lines. The manufacturer does not make any anti microbial claim. The CE mark is however accompanied by a number of a notified body, implicating that the product is at least a class IIa medical device.

Product e
"An aldehyde free concentrate for the disinfection and cleaning of surfaces. Good cleaning capability, biological degradable." Since the product is not a medical device it is correctly not CE marked, but is it also not registered under the Pesticides act.

Product f
Cleaning wipes for the disinfection of instruments and hard surfaces. The product is CE marked, without the identification number of a notified body. The product is recommended for the disinfection of instruments, but also all objects that need rapid disinfection during work like handles, surgical lamps, water taps, toilet seats, operating panels etc. The application is clearly not limited to medical devices, the product should therefore not be CE marked.

Appendix 5 Response from the manufacturers

Manufacturer	Response
1.	The manufacturer has followed the CE conformity procedure described in Annex V of the MDD. The product has been tested in 1992 to the valid guidelines of the DGHM at the time.
2.	The manufacture sent copies of the certificates for the quality assurance system for the design, production an sales of chemical disinfectants. The certificate is complemented with a list of the products that are produced under the quality assurance system. A number of disinfectants are listed that have a broader application than the disinfection of medical devices (e.g. sprays for surface disinfection). No information about the product tests has been given.
3.	The manufacturer states that the disinfecting wipes are certificated using annex II of the MDD. The product has been tested to the guidelines of the DGHM and DVV/BASG as well as the French standard NF T 72170. The product has been tested by four third parties.
4.	The manufacturer states that annex 5 of the MDD has been followed. The product has been tested to the guidelines of the DGHM.
5.	The manufacture of disinfecting wipes has sent copies of the test reports from three third parties. The product fulfils the requirements of the DGHM with a contact time of 2 minutes. The product has been tested for virucidal activity with the 'antigen inactivation test'.
6.	The manufacture states that CE conformity procedure in annex V of the MDD is used. No information about the product tests was given.
7.	The manufacture provided a list of the tests that have been performed on the product or with the product. The tests were performed by a number of different persons/organisations. The list also mentions the test organisms that have been used in the tests. The manufacturer refered to national standards, which were identified by the notified body as the DGHM guidelines. The manufacture sent copies of the certificates for the quality assurance system for the design, production an sales of chemical disinfectants. The certificate is complemented with a list of the products that are produced under the quality assurance system. A number of disinfectants are listed that have a broader application than the disinfection of medical devices (e.g. sprays for surface disinfection).
8.	The manufacture stated that all product information has been evaluated by the notified body. In case of a problem with one of the products from his company he advises to seek contact with "our competent authority". The manufacturer did not provide any information on the tests performed on his product.
9/10.	Manufacture did not respond to the questions (2x)