

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.1/Rec5
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Title:	Placing on the market of fully refurbished medical devices
Chapter:	2.1 Scope, field of application, explanation of terms

Text:	<i>Definition of “manufacturer”:</i> “manufacturer” means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. <u>The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose with a view to their being placed on the market under his own name.</u> This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient. (Underlined part of special interest to this Recommendation.) <i>Definition of “placing on the market”:</i> “placing on the market” means the <u>first making available</u> in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished.
Key words:	fully refurbished, manufacturer, placing on the market, first making available

1. Purpose of this Recommendation

The term “fully refurbished”/“fully refurbishes” is mentioned in the above definitions which are contained in the Medical Devices Directive (MDD) and in the In Vitro Diagnostic Medical Devices Directive (IVDD), but is not itself defined. However, it is important for both industry and regulators to understand the meaning of “fully refurbish” and to distinguish such activity from normal repair and maintenance operations. The purpose of this recommendation is to give guidance in that respect.

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	Article/ Annex:	Reference to standards:
AIMD	as amended by article 21 of MDD	
MDD	Article: 1.2(f), 1.2(h)	
IVDD	Article: 1.2(f), 1.2(i)	

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2. Background

It is relevant to take note of the following common practices in the supply and use of medical devices.

- (a) The issue of “refurbishment” or „full refurbishment“ applies mainly to reusable devices. Single use devices are, by definition, normally used in their original state and then discarded.
- (b) It is common for a reusable medical device to require routine service and repair in order to maintain it in good and safe operating condition. Such repair and maintenance may be carried out by the owner, the manufacturer or a third party. In each case, it must be distinguished from “full refurbishment”, since the Medical Devices Directives are not intended in any way to obstruct such normal repair and maintenance operations.
- (c) A person sending a medical device for service or repair may or may not receive the same item back. Often a manufacturer will immediately replace the device with another of the same type in order that the user is not left without equipment. Alternatively, the manufacturer may operate a pool of devices of the same kind into which the repaired device is placed. The user may receive any one of those ‘pool’ devices in return for the one he sent for repair. This procedure does not necessarily mean that the replacement device has been fully refurbished, even if it has been serviced or repaired and checked for proper working order.
- (d) In contrast to the above cases, none of which would necessarily lead to the conclusion that the device has been fully refurbished, there is an established market for using certain used devices (normally expensive capital equipment) as the basis for the construction of a new device the design of which may or may not be similar to that of the original device. Such an operation may be carried out by the original manufacturer or by a third party. In such a case, it must be viewed either as the manufacture of a new device or the “full refurbishment” of an existing device.

(In this context, it should be noted that the original French text of the MDD uses the phrase „remis à neuf“, i.e. return to a new condition.)

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3. The Principle of “Placing on the market of fully refurbished medical devices ”

It is important to note that the Medical Devices Directives refer to devices which are both “fully refurbished” and “placed on the market”. Clearly this is **not** the case with a device which is simply repaired or maintained.

”Placing on the market” means making available of a device for the first time with a view to distribution and / or use – ”regardless” of whether that device is new or ”fully refurbished”. A device which has been used and is subsequently repaired is not made available for the first time: it is merely returned to the market place.

“Full refurbishment” occurs when a device is completely rebuilt or made as new from used devices and is assigned a new useful life.

In other words, it is necessary to look at the intent in order to determine whether a device has been fully refurbished or not. If the intent was to create a renewed device and place it on the market under the refurbisher’s name, then this device is considered to be “fully refurbished” and the refurbisher becomes the „manufacturer“ under the Directive and so must comply with the requirements of the Directive in order first to make a declaration of conformity and to affix the CE marking.

4. How to decide if a “fully refurbished“ device is “placed on the market“

4.1 The following criteria if fulfilled in combination, indicate that a device is „fully refurbished“ and placed on the market:

- (a) the device is “fully refurbished“. This typically involves:
- stripping into component parts or sub-assemblies;
 - checking their suitability for reuse;
 - replacement of components/sub-assemblies not suitable for reuse;
 - assembly of the reclaimed and/or replacement components/sub-assemblies;
 - testing of the assembled device against either original or revised release criteria;

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- the identification of the „fully refurbished“ device by appropriate means;

- (b) the „fully refurbished“ device is placed on the market¹ under the name of the person responsible for the full refurbishment, without changing the intended use.

Note: If the intended use is changed, then the device necessarily becomes a new device, subject to the provisions of the MDD or IVDD.

4.2 A device is not fully refurbished and subsequently placed on the market if either of the criteria at 4.1 is not met. Examples of where at least one of the two criteria is not met include:

- normal repair/maintenance activities (performed by either the original manufacturer/distributor or a third party, including the replacement of original components/sub-assemblies with new or reclaimed spare parts, either from the original manufacturer or another source);
- repair/replacement schemes, in which the user receives a serviced or repaired device which is not necessarily his original device;
- new items repaired before sale or supply (for instance to repair transit damage, in accordance with the manufacturer's instructions);
- refurbishing of a medical device by the user for his own use;
- sale or supply of devices which have already been placed on the Community market (e.g. pre-owned or „second-hand device“), including those where some repair and/or maintenance is necessary to regain their operational condition.

Note: In some cases, software may itself be a medical device and may need to be considered separately.

¹ „Placing on the market“ is defined in the Directive. Additional guidance is given in *Guide to the implementation of Directives based on new approach and global approach* (ISBN 92-828-7500-8 (1999) (so called „blue vademecum“)

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Rev. 1: Meeting of NBR Group, Brussels, June 26 & 27 1997:

Based on S/04/96 of the "Consensus Statements" document there was a discussion concerning „refurbished“ and „fully refurbished“. Result: this resolution will be developed as a NB-MED recommendation by working group (Mr. Barrow, Mr. Junker, Dr. Lehmann, Dr. Wallroth) until NBRG-Meeting on September 29./30., 1997. Document Med-NB/18/95 should be considered.

Meeting of ad hoc group "fully refurbished", Lübeck, September 26, 1997:

The ad hoc group created a draft document of this subject for further discussion in the NBR group.

Meeting of NBR Group, Essen, September 29 & 30 1997:

Based on above mentioned draft document it was decided to do some minor additions/changes and to fit the document in the new *recommendations nomenclature system* (chapter 2.1 *Scope, field of application, explanation of terms*). Therefore the recommendation gets the new number **NB-MED/2.1/R5**. NBRG agreed to send the document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1997.

Revision no: 1

Confirmed to be at stage: 2

Rev. 2: Notified Body Meeting, Brussels, November 18 & 19. 1997:

Some minor changes has to be considered:

Page 2, 1st sentence should read "... which is subsequently "placed on the market" and which ..."

Page 2, 2.1 (a) , 1st sentence should read „(a) a device is "fully refurbished", that is returned to a condition "as new"; ...“

NB-MED decided to consider and to discuss the comments made by Mr. Reincke/EUROCAT

„I principally agree to the recommendation but I am concerned about 2.2, dash 5.

It should not be interpreted that way that a manufacturer can „upgrade“ the device whether it is hard- or software without verifying carefully if the criteria for CE-marking are still fulfilled. If in doubt he should contact the involved NB for decision.

It is true that an upgraded device must not be fully refurbished, but an upgraded device can easily become subject of a (partly) new conformity assessment. In the case of software it depends strongly on the technique of programming to decide if „the regulatory status of the device is affected“. Software will never be „replaced“ like a spare part, because software will not be destroyed by use. But an upgrade can mean new functionality and

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less „bugs“. In many cases new bugs are generated. This s subject of the updated risk-analysis.

The NB-MED should be very careful when using the term „upgrade“.

and the comments which still will be made by the industrial federations (COCIR) at the next NBRG meeting on 22./23.01.98. Results should be presented at the next NB-MED meeting.

Confirmed to be at stage: 1

Rev. 3: Meeting of NBR Group, Brussels, January 22 & 23 1998:

1st: comments made by Mr. Dalgetty/AMTAC were tabled:

„The word ‘refurbish’ means to renovate, re-equip or restore. The word ‘fully’ can have a number of similar meanings, depending on the context in which it is used. The two most relevant meanings in this instance are

1. to the greatest degree or extent and
2. amply; adequately.

I would suggest that the term ‘fully refurbished’ should be taken to mean ‘adequately renovated, re-equipped or restored’. A ‘fully refurbished medical device’ would, therefore, be a medical device which had been adequately renovated, re-equipped or restored to be capable of fulfilling its (original?) intended purpose.

Functional medical devices which are subject to maintenance, servicing or repair, are not ‘fully refurbished’ by virtue of those activities. I would suggest that this term should only be applied to devices which have been withdrawn from the market or use for the purpose of complete evaluation of function and appearance and subsequent restoration of function and appearance (including expected life span?). This process may include enhancement or modification of the device to better achieve the intended purpose, but changes to the intended purpose (restriction or enlargement) would require the full provisions of the MDD being invoked as if the device were new. Enhancement or modification would obviously require design review and risk analysis, etc.

Full refurbishment can take place without change of ownership, since this is not directly or indirectly implied or referred to in the relevant text of the MDD. What is stated in the Directive is that the act of fully refurbishing a device is undertaken with a view to placing the product on the market (i.e. distribution and/or use) under his own name.

Remembering that the purpose of the MDD is to ensure an internal market in medical devices, the Directive should be invoked when:

1. A fully refurbished device is offered for sale, hire or use by an entity (natural or legal person) who has undertaken the refurbishment, but was not the original manufacturer.
2. A fully refurbished device is offered for sale, hire or use to a different user entity (natural or legal person) than that which was in control of the device prior to full refurbishment.

The situation where a ‘manufacturer’ restores a medical device for a user so that the device continues to achieve the original intended purpose with the device being returned to the user, should not directly invoke the MDD because the device is not being placed on the market. However, in such cir-

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cumstances, the 'manufacturer' must be able to demonstrate that the device complies with the Essential Requirements.

In view of the foregoing, I have several criticisms of the draft Recommendation. In particular:

Page 2/4 2nd paragraph

⇒ 1st sentence replace 'largely' with 'such as'

⇒ 3rd sentence replace 'rebuilding' with 'activity'

Page 2/4 Clause 2

⇒ Clause 2.1 needs to be completely re-written. It should contain a definition of 'fully refurbished' and examples such as I have suggested as to when the MDD is invoked. I do not agree with 2.1(b)

Page 3/4 Clause 2.2

⇒ I would suggest that this clause should also be re-written to merely give examples of activities which do not constitute fully refurbishing.

⇒ I would object to the inclusion of

- the second indent example (serial numbers should be unique and replacement of a device may require the full MDD provisions).
- the third indent example (confusing, not relevant and possibly wrong).
- the fifth indent example (confusing and in need of more detailed discussion)

Page 4/4 Clause 2.2 Continued

⇒ Delete the first sentence.

⇒ Delete the last indent example, which is extremely confusing.

⇒ I would suggest that the Recommendation be concluded with a paragraph reminding those involved with the repair, servicing, maintenance and calibration of devices that their activities should be organised and managed in a manner which ensures that the device continues to fulfil its intended purpose."

2nd: a new proposal made by EUCOMED and presented by Mr. Barrow was tabled:

„1. Purpose and Recommendation

The term "fully refurbished"/"fully refurbishes" is mentioned in the above definitions which are contained in the Medical Devices Directive MDD [and in the draft IVDD], but is not itself defined. However, it is important for both industry and regulators to understand the meaning of "fully refurbish" and to distinguish such activity from normal repair and maintenance operations. The purpose of this recommendation is to give guidance in that respect.

2. Background

It is relevant to take note of the following common practices in the supply and use of medical devices.

(a) The issue of "refurbishment" applies mainly to reusable devices and is particular to medical equipment. Single use devices are, by definition, normally used in their original state and then discarded.

(b) It is common for reusable medical equipment to require routine service and repair in order to maintain it in good and safe operating condition. Such repair and maintenance may be carried out by the owner, the manufacturer or a third party. In each case, it must be distinguished from

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“refurbishment”, since the Medical Device Directives are not intended in any way to obstruct such normal repair and maintenance operations.

(c) A person sending a piece of medical equipment for service or repair may or may not receive the same piece of equipment back. Often a manufacturer will immediately replace the device with another of the same type in order that the user is not left without equipment. Alternatively, the manufacturer may operate a pool of devices of the same kind into which the repaired device is placed. The user may receive any one of those ‘pool’ devices in return for the one he sent for repair.

(d) In contrast to the above cases, none of which involves refurbishment, there is an established market for using certain devices (normally expensive capital equipment) which have reached the end of their useful life as a basis for building new and/or different equipment. Such devices may be stripped down and their component parts used in the construction of a new device the design of which may or may not be similar to that of the original device. Such an operation may be carried out by the original manufacturer or by a third party. In either case, it may be viewed either as the manufacture of a new device or the “full refurbishment” of an existing device. (In this context it should be noted that the original French text of the Medical Devices Directive uses the phrase “remis à neuf”, i.e. return to new condition).

3. The Principle of “Refurbishment”

It is important to note that, as used in the Medical Devices Directives, devices are only “fully refurbished” if they are “placed on the market” by the person carrying out the refurbishment under his name. Clearly this is **not** the case with a device which is simply repaired or maintained.

“Placing on the market” means putting a device into distribution in the Community for the first time. A device which has been used and is subsequently repaired is not placed into distribution for the first time: it is merely returned to a user in the market place.

Accordingly, “full refurbishment” only occurs when (a) a device is completely rebuilt or made as new from used devices and (b) the renewed product is placed into distribution for the first time in the EU by the person carrying out the refurbishment and under that person’s name.

In other words, it is necessary to look at the intent in order to determine whether a device has been refurbished or not. If the intent is to create a renewed product and place it into distribution for the first time under the refurbisher’s name, then the device is considered to be “fully refurbished” and the person responsible must comply with the requirements of the Directive in order first to make a declaration of conformity and to affix the CE marking. However, if this is not the case, there is no “full refurbishment”.

4. Practical Examples

4.1 Typically, the following will take place if a device is to be fully refurbished and subsequently placed on the market.

(a) the device will be completely rebuilt, that is returned to a condition as “new”. This will typically involve:

- stripping into component parts or sub-assemblies;
- replacement of components/sub-assemblies not suitable for reuse;

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- assembly of the reclaimed and/or replacement components/sub-assemblies;
- testing of the assembled device against either original or revised release criteria;
- the identification of the device as a rebuilt device and allocating a new serial/lot number.

(b) Ownership of the fully refurbished device will change from the original user/owner to the person carrying out the refurbishment.

(c) The device will be placed on the market as a “fully refurbished” device under the name of the person who is responsible for the refurbishment, without changing the intended use. (If the intended use changes, then the device becomes a “new” device, subject to the full provisions of the MDD [or draft IVDD]).

The person who carries out these activities is treated as a “manufacturer” as defined by the MDD [or draft IVDD] and must ensure that:

- (i) the applicable conformity assessment requirements of the MDD [or draft IVDD] are met, and
- (ii) the device meets with essential requirements that apply to it.

4.2 Examples of where a device is not regarded as being fully refurbished include:

- normal repair/maintenance activities (performed by either the original manufacturer/distributor or a third party, including the replacement of original components/sub-assemblies with new or reclaimed spare parts, either from the original manufacturer or another source, including technical specification changes which do not affect the regulatory status of the device but which may adapt the device to technical progress);
- repair/replacement schemes, in which the user receives a repaired device which is not necessarily his original device, although the serial number may be retained;
- the making available of loan equipment or replacement devices which may have been repaired/serviced prior to being made available;
- new items repaired before sale (for instance to repair transit damage, in accordance with the manufacturer's instructions);
- software upgrades which do not affect regulatory status of the device. Note: if new/upgraded software does not originate from the original equipment manufacturer, then the software itself is likely to be a new device or an accessory and subject to the full provisions of the MDD [or draft IVDD];
- refurbishing of a medical device by or on behalf of the user without change of ownership and without placing the device on the market;
- amendments to labelling which take into account experience with the device or adapt it to technical progress;
- sale of second-hand devices which have already been placed on the Community market, including those where some repair and/or upgrade is necessary to maintain them to operational condition.“

3rd: comments made by Mr. van Pagée/COCIR were tabled:
During discussions the three tabled documents

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- rev. 2
- comments made by Mr. Dalgetty
- new proposal made by EUCOMED

were fitted together in a suitable way to a new draft recommendation. The comment made by COCIR was covered by rev. 2.

NBRG agreed to send the revised document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in March 1998.

New revision no: 3

Confirmed to be at Stage: 2

Rev. 4: Notified Body Meeting, Brussels, March 3 & 4, 1998:

The tabled document (NBM/7/98) was presented. Prof. Leitgeb wished more clarification concerning the differences between "maintenance" and "refurbishment" (chapter 4). The very important subject that placing on the market is combined with change of ownership needs also some clarification (a) page 3, first paragraph, should be read: "... A device which has been ...: it is merely returned to the same user in the market place.", because there is no change of ownership; b) page 4, chapter 4.2, 2nd dash seems to be a change of ownership). Mr. Barrow explained the combination of "fully refurbishing" and "placing on the market for the first time" is the important key. Mr. Ruys/KEMA asked for the practicable approach how procedures/annexes have to apply for the different kinds of "fully refurbished devices" to get a CE-mark. Mr. Anselmann referred that the question of ownership is not a criteria for placing on the market at all. In general Mr. Anselmann would like to advice the NB-MED not to draft documents in such way "this is the "case" if criteria a), b), c) are met". NB-MED should not elaborate guidances so strongly; "smooth" guidances are wished. NB-MED decided to consider and to discuss the comments made and the comments which still will be made by the industrial federations (especially offered by Dr. Dörr/EDMA which will be made by legal experts) at the next **NBRG** meeting on 20./21.04.98. Also the inquiry NBM/11/98 should be considered.

Confirmed to be at Stage: 1

Meeting of NBR Group, Brussels, April 20 & 21 1998:

Comments made by Mr. Vercooteren/EUCOMED were discussed and considered. A new draft (made by Dr. Dörr/EDMA) was tabled, discussed; the most recommendations of this draft document were considered in the older issue (NBM/7/98).

NBRG agreed to send the revised document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in June 1998.

New revision no: 4

Confirmed to be at Stage: 2

Notified Body Meeting, Brussels, June 09 & 10, 1998:

The document was tabled on the Notified Body Meeting on 09./10.06.98. The document was approved by the NB-MED plenary.

Confirmed at stage 3.

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Rev. 5: Notified Body Meeting, Brussels, November, 2 & 3, 1999:
The NBRG was asked to rework the NB-MED Recommendations in light of the IVD-directive.

Meeting of NBR Group, Cologne, February 3, 2000:

The work results of a small task force (task: reworking the Recommendations in light of IVDD) were presented to that NBRG-meeting.

The tabled revised working document (without revision no.) was discussed and some criticism was made. Mr. Dalgetty promised to send his written comments to NBRG. NBRG agreed that the document should not be presented to the NB-MED Plenary meeting. Comments will be discussed on occasion of the next NBRG-meeting.

Meeting of NBR Group, Brussels, April 10 & 11, 2000:

Dr. Dörr presented a new working document and explained the changes which should be made in light of IVDD; in parallel he referred to the comments made by Mr. Dalgetty (see NBRG/176/00). After the discussion it was agreed that all comments were considered in the new revised draft document. NBRG agreed to change only the wording necessary to include IVDs under the scope of this document.

NBRG agreed that the document, as discussed and - during the meeting - revised, should be presented for adoption at the June NB-MED Plenary meeting.

Revision no: 5

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Notified Body Meeting, Brussels, June 6 & 7, 2000:

The document (NBM/57/00) was approved by the NB-MED plenary.

Confirmed at stage 3.

Revision no: 5



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