



PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Registration of Manufacturers and other Parties and Listing of Medical Devices

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: October 20, 2008

1	Table of Contents	
2		
3	1.0 Introduction.....	4
4	2.0 Rationale, Purpose and Scope.....	5
5	2.1 Rationale	5
6	2.2 Purpose.....	5
7	2.3 Scope.....	6
8	3.0 References.....	6
9	4.0 Definitions.....	6
10	5.0 Registration Requirements	7
11	5.1 General.....	7
12	5.2 Parties subject to registration	7
13	5.3 Timing of registration	8
14	5.4 Information to be submitted for registration purposes.....	8
15	5.5 Role of the Regulatory Authority	9
16	5.6 Role of the Registrant	9
17	6.0 Medical Device Listing Requirements	10
18	6.1 General.....	10
19	6.2 Parties subject to listing requirements	10
20	6.3 Timing of listing	10
21	6.4 Information to be submitted for listing purposes.....	11
22	6.5 Role of the Regulatory Authority	12
23	6.6 Role of the Registrant	12
24		
25		

1 **Preface**

2

3

4

5

6

7

8

9

10

11

12

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution, translation or use of this document. However, incorporation of this document, in part or in whole, into any other document does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

1 1.0 Introduction

2 The objective of the Global Harmonization Task Force (GHTF) is to encourage
3 convergence at the global level in the evolution of regulatory systems for medical devices in
4 order to facilitate trade whilst preserving the right of participating members to address the
5 protection of public health by regulatory means considered the most suitable.
6

7 The primary way in which the GHTF achieves its goals is through the production of a
8 series of guidance documents that together describe a global regulatory model for medical
9 devices. The purpose of such guidance is to harmonize the documentation and procedures
10 that are used to assess whether a medical device and its manufacturer conform to the
11 regulations that apply in each jurisdiction. Eliminating differences between jurisdictions
12 decreases the cost of gaining regulatory compliance and allows patients earlier access to new
13 technologies and treatments.
14

15 This document has been developed to encourage and support global convergence of
16 regulatory systems. It offers:

- 17 • recommendations for the establishment and maintenance of registration and
18 medical device listing databases by the Regulatory Authority;
- 19 • a harmonized definition of, and recommendations for, registration of medical
20 device manufacturers and/or other parties in the supply chain; and
- 21 • recommendations for the listing with a Regulatory Authority of all medical
22 devices placed on the market by those parties.

23 This document is intended for use by Regulatory Authorities (RAs) and the registrants
24 responsible for providing registration and medical device listing information to the
25 authorities, and will provide benefits in establishing, in a consistent way, an economic and
26 effective approach to the control of medical devices in the interest of public health. It seeks
27 to strike a balance between the responsibilities of Regulatory Authorities to safeguard the
28 health of their citizens and their obligations to avoid placing unnecessary burdens upon the
29 industry.
30

31 The GHTF supports and encourages regulatory harmonization but recognises that some
32 RAs may have to reflect different local needs when considering the recommendations in this
33 guidance document. However, RAs that are developing registration and listing procedures or
34 amending existing ones are encouraged to consider the adoption of the recommendations
35 described in this document, as this will help to reduce the diversity of practices worldwide
36 and facilitate the process of harmonization.
37

38 Where another GHTF guidance document is referenced within this text, its title is
39 italicised for clarity.
40

41 Comments or questions about this document should be directed to the Chair of GHTF
42 Study Group 1 whose contact details may be found on the GHTF web page¹.

¹ www.gh tf.org

1 **2.0 Rationale, Purpose and Scope**

2 **2.1 Rationale**

3 In many jurisdictions where regulations for medical devices are first introduced, the
4 initial step in the process is often the collection by the RA of information relating to:

- 5 • the range and types of devices already on the market,
- 6 • the manufacturers of these devices, and
- 7 • other parties responsible for supplying them to the market in that jurisdiction.

8 Having established databases that contain such information, these are updated in
9 response to new medical devices being placed on the market and any other changes to the
10 information provided in the first instance.

11
12 The collection and retention of this information on manufacturers / importers /
13 distributors (hereafter referred to as ‘registration’) and the types of medical devices marketed
14 by those parties (hereafter referred to as ‘listing’) are fundamental elements of regulatory
15 control². Where available resources are limited, registration and listing may be the only, or
16 primary, regulatory control.

17
18 Most GHTF Founding Members have incorporated registration and listing requirements
19 into their medical device regulations. The information held is useful in facilitating regulatory
20 actions such as field safety corrective actions and recalls. It may also be used for law
21 enforcement purposes. To date, these systems are not harmonized.

22
23 When registration and listing information, in whole or part, is publicly accessible, it
24 allows device purchasers or users of medical devices to identify products available to them
25 and determine the identity and location of their manufacturers and/or distributors and/or
26 importers.

27 **2.2 Purpose**

28 In its document ‘Strategic Direction (2006)’, the GHTF Steering Committee established
29 the general goal of mutual acceptance of common data by regulators. Among the examples
30 the Committee gave was “information on ‘registration’ (of medical device manufacturers and
31 importers) and ‘listing’ (of medical devices placed on the market under a regulator’s
32 jurisdiction)”.

33
34 This guideline offers definitions for the terms ‘registration’ and ‘listing’. It clarifies the
35 roles and responsibilities of those entities involved in placing a medical device on the market,
36 such as the manufacturer, authorised representative, distributor and importer, with respect to
37 registration and listing. It also provides guidance on the data content for registration and
38 listing.

39

² See GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*

1 This document will have as its audience RAs and the regulated industry. It should
2 assist jurisdictions introducing medical device regulations for the first time, those revising
3 existing regulations, and should improve the clarity of existing GHTF harmonized guidelines.

4 **2.3 Scope**

5 This guidance applies to all products that fall within the GHTF definition of a medical
6 device that appears within the GHTF document *Information Document Concerning the*
7 *Definition of the Term “Medical Device”*, including those used for the in vitro diagnostic
8 examination of specimens derived from the human body.

9 **3.0 References**

10 GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term*
11 *“Medical Device”*.

12
13 GHFT/SG1/N055 *Definition of the Terms “Manufacturer”, “Authorised Representative”,*
14 *“Distributor” and “Importer”*.

15 **4.0 Definitions**

- 16 1. **Listing:** the process whereby a party submits information to the Regulatory Authority in
17 a jurisdiction, regarding the identification of a medical device(s) that is supplied to the
18 market in that jurisdiction.
- 19 2. **Supply(ing) to the market:** the making available, in return for payment or free of charge,
20 of a device, other than a device intended for clinical or performance evaluation, with a
21 view to distribution and/or use on the market.
- 22 3. **Registration:** the process by which a party submits information to the Regulatory
23 Authority in a jurisdiction, regarding the identification and establishment location(s) of
24 the manufacturer and other parties, responsible for supplying a medical device(s) to the
25 market in that jurisdiction.
- 26 4. **Registrant:** any party required to provide information for registration or listing purposes.

1 **5.0 Registration Requirements**

2 **5.1 General**

3 5.1.1 Establishment registration is intended to provide information on the parties that have
4 been, or will be, supplying medical devices to the market that is within the RA's
5 jurisdiction.

6 5.1.2 In establishing the registration process described in this guidance document, the RA
7 should clearly identify which of the parties listed in Section 5.2.1 is required to
8 provide information to it.

9 5.1.3 Providing establishment registration information to the RA does not remove from the
10 registrant its obligation to comply fully with all the regulations that apply to it within
11 the jurisdiction.

12 **5.2 Parties subject to registration**

13 5.2.1 Medical device manufacturers, importers and distributors may be subject to
14 registration requirements³.

15 **Notes:**

16 1. While retaining responsibility, the manufacturer may authorise a representative to
17 fulfil the registration requirements on its behalf.

18 2. The benefit to the RA of registering distributors is likely to depend on both the
19 jurisdiction and the type of medical device the distributor will supply to the
20 market. In most situations, a decision to register 'all distributors' will require
21 significant resources and lead to an unwieldy database. When specifying which
22 distributors, if any, are subject to registration requirements, the RA should take
23 account, for example, of:

- 24 • the purpose of collecting information on distributors;
- 25 • whether the database should be restricted to certain medical devices only,
26 specified, for example, by risk class;
- 27 • whether registration of distributors is required when the manufacturer is
28 located in the jurisdiction;

³ For definitions of the terms 'manufacturer', 'authorised representative', 'distributor' and 'importer' refer to the SG1 guidance document GHTF/SG1/N055.

- 1 • where the medical device is to be imported into the jurisdiction, whether
- 2 registration is restricted to the importer only;
- 3 • whether registration is restricted to only those distributors having a legal
- 4 contract with either the manufacturer or the importer of the medical
- 5 device(s) to be supplied to the market;
- 6 • whether registration excludes distributors involved only in the supply of
- 7 consumer products to the end user, e.g. domestic retail pharmacies;
- 8 • the likely size, complexity and maintenance of the resulting database.
- 9

10 **5.3 Timing of registration**

11 When the establishment registration database is first established, registrants will be
12 allowed an interval to provide registration information. Thereafter, the registrant should
13 submit information for registration purposes before it is involved in the supply of any medical
14 device to the market for the first time.

15 **5.4 Information to be submitted for registration purposes**

16 For the purposes of registration and, irrespective of device classification, each registrant
17 should submit the following information to the RA.

- 18 1. An indication of whether the registrant is a manufacturer, an authorised
19 representative acting on the manufacturer's behalf, an importer or a distributor of
20 medical devices supplied to the market of the jurisdiction where the information
21 is being collected. Some registrants will fall into more than one of these
22 categories.
- 23 2. Name and contact details (i.e. postal address in a format that allows location to be
24 established⁴, telephone number and e-mail address) of the registered place of
25 business of the registrant together with the name and post held of the person
26 responsible for the registration within that organisation .
- 27 3. Where registration is delegated to an authorised representative, the authorised
28 representative should provide the name and contact details (i.e. postal address in a
29 format that allows location to be established, telephone number and e-mail
30 address) of the registered place of business of the manufacturer(s) on whose
31 behalf it is acting, together with the name and post held of the person responsible
32 for the registration within the manufacturer's organisation.
- 33 4. Where the registrant is a manufacturer who supplies more than one finished
34 medical device to the market of the jurisdiction where the information is being
35 collected, **and** the different types of finished medical devices are manufactured at
36 different sites, it should provide the name and contact details (i.e. postal address
37 in a format that allows location to be established, telephone number and e-mail
38 address) of each site, together with the name and post held of the person(s)
39 responsible for the registration within the manufacturer's organisation.

⁴ The provision of a PO Box number alone is insufficient both here and elsewhere within this document.

- 1 5. An indication that the information provided is either a new entry or an update of
2 previously submitted information. If the second situation applies, the registration
3 code allocated to the registrant (see Section 5.5 bullet 8) should be provided.
- 4 6. The date when the information is submitted.

5 **5.5 Role of the Regulatory Authority**

6 5.5.1 The RA in a jurisdiction is the party to which the registrant should submit registration
7 information. The RA is responsible for:

- 8 • identifying which of the parties listed in Section 5.2.1 is required to provide
9 information to it;
- 10 • specifying the information it requires from each registrant (see Section 5.4);
- 11 • specifying the format, mechanism and frequency with which the registration
12 information is to be provided.;
- 13 **Note:** RAs are encouraged to establish an internet-based system for collection of
14 registration information.
- 15 • designating the language(s) requirements for the registration information to be
16 provided;
- 17 • providing a mechanism that allows incorporation of either a new entry or updated
18 information, into a searchable database, and ensuring such entries are
19 incorporated within 30 days of the information being provided;
- 20 • the development, maintenance and security of the database containing the
21 entrusted data;
- 22 • ensuring the recorded data reflects accurately the information provided by the
23 registrant;
- 24 • assigning a registration code to each registrant;
- 25 • acknowledging to the registrant that the required information has been received
26 and is acceptable;
- 27 • specifying whether only itself and the registrant have access to the registration
28 information, or whether some or all of the information held may be accessed by
29 others, e.g. purchasers of medical devices;
- 30 • on a periodic basis, not more frequent than annually, requesting each registrant to
31 confirm that the information provided for registration purposes continues to be
32 accurate.

33 **5.6 Role of the Registrant**

34 5.6.1 The registrant is required to:

- 35 • provide the RA with the registration information specified in Section 5.4;
- 36 • attest to its accuracy;
- 37 • update the information provided within 30 calendar days of the occurrence of any
38 change, or when requested to do so by the RA, in order to maintain the accuracy
39 of the registration information;

- 1 • respond to the RA’s request to confirm that the information provided for
2 registration purposes continues to be accurate.

3 **6.0 Medical Device Listing Requirements**

4 **6.1 General**

5 6.1.1 Medical device listing is intended to provide information on medical devices that have
6 been, or will be, supplied to the market that is within the RA’s jurisdiction.

7 6.1.2 In establishing the listing process described in this guidance document, the RA should
8 clearly identify which of the parties listed in Section 6.2 is required to provide
9 information to it.

10 6.1.3 Providing medical device listing information to the RA does not remove from the
11 registrant its obligation to comply fully with all the regulations that apply to it within
12 the jurisdiction.

13 **6.2 Parties subject to listing requirements**

14 6.2.1 Where the manufacturer is located in the same jurisdiction as the RA, the
15 manufacturer is responsible for providing listing information. While retaining
16 responsibility, the manufacturer may authorise a representative to fulfil the listing
17 requirements on its behalf.

18 6.2.2 Where the manufacturer is located in a different jurisdiction as the RA, each
19 manufacturer, importer or the authorised representative is responsible for providing
20 listing information to the RA.

21 **6.3 Timing of listing**

22 When the medical device listing database is first established, registrants will be allowed
23 an interval during which they should provide information on those medical devices that
24 are being supplied to the market at the time of registration. Thereafter, the registrant
25 should submit listing information for each medical device it intends to supply to the
26 market, before that medical device is supplied for the first time.

27
28 **PUBLIC COMMENT IS REQUESTED ON THE FOLLOWING SUBJECT –**
29 **When first established, should the listing database include medical devices that are no**
30 **longer supplied to the market but continue to be in use? For example, the text could be**
31 **modified to read “..... on those medical devices that have been supplied to the market**
32 **within the past 10 years”.**
33

1 **PUBLIC COMMENT IS REQUESTED ON THE FOLLOWING SUBJECT –**
2 **After the database has been established, should the registrant be allowed time to**
3 **provide listing information after the medical device has been supplied for the first time**
4 **(e.g. within 30 days)?**

5 **6.4 Information to be submitted for listing purposes**

6 For the purposes of medical device listing, the registrant should submit the following
7 information to the RA.
8

- 9 1. An indication of whether the registrant is a manufacturer, an authorised
10 representative acting on the manufacturer's behalf, an importer, or a distributor of
11 medical devices supplied to the market of the jurisdiction where the information
12 is being collected, and their associated registration codes.
- 13 2. Name and contact details (i.e. postal address in a format that allows location to be
14 established, telephone number and e-mail address) of the registered place of
15 business of the registrant together with the name and post held of the person
16 responsible for the provision of listing information within that organisation.
- 17 3. Where the provision of listing information is delegated to an authorised
18 representative, the authorised representative should provide the name and contact
19 details (i.e. postal address in a format that allows location to be established,
20 telephone number and e-mail address) of the registered place of business of the
21 manufacturer(s) on whose behalf it is acting, together with the name and post held
22 of the person responsible for the provision of listing information within the
23 manufacturer's organisation.
- 24 4. Where the registrant is an importer or a distributor specified by the RA under the
25 provisions of Section 5.2.1, it should provide the name and contact details (i.e.
26 postal address in a format that allows location to be established, telephone
27 number and e-mail address) of the registered place of business of the
28 manufacturer(s) of the medical device(s) for which it is providing listing
29 information together with the name and post held of the person responsible for
30 the provision of listing information within the manufacturer's organisation.
- 31 5. List, by the device code allocated through an internationally recognised coding
32 system⁵ each of the finished medical devices to be manufactured within, or
33 imported into, the jurisdiction and indicate whether any marketing authorisation
34 exists within that jurisdiction.
- 35 6. An indication that the information provided is either a new entry or an update of
36 previously submitted information. If the second situation applies, the listing code
37 previously allocated to the medical device (see Section 6.5 bullet 8) should be
38 provided.

⁵ The Global Medical Device Nomenclature (GMDN) provides the use of generic descriptors for the identification of medical devices and other healthcare related products. The nomenclature system is managed by the [GMDN Agency](#). The code is based on the international standard EN ISO 15225.

1 **Note:** the RA may retain a database of medical devices that are no longer being
2 supplied to the market in an archived form.

3
4 7. The date when the listing information is submitted.

5 **6.5 Role of the Regulatory Authority**

6 6.5.1 The RA in a jurisdiction is the party to which the registrant should submit listing
7 information. The RA is responsible for:

- 8 • identifying which of the parties listed in Section 6.2 is required to provide
9 information to it;
- 10 • specifying the information it requires from each registrant (see Section 6.4);
- 11 • specifying the format, mechanism and frequency with which the medical device
12 listing information is to be provided;

13 **Note:** RAs are encouraged to establish an internet-based system for collection of
14 medical device listing information.

- 15 • designating the language(s) requirements for the listing information to be
16 provided;
- 17 • providing a mechanism that allows incorporation of either a new entry or updated
18 information, into a searchable database, and ensuring such entries are
19 incorporated within 30 days of the information being provided;
- 20 • the development, maintenance and security of the database containing the
21 entrusted data;
- 22 • ensuring the recorded data reflects accurately the information provided by the
23 registrant;
- 24 • assigning a code to each medical device that is listed in the database;
- 25 • acknowledging to the registrant that the required information has been received
26 and is acceptable;
- 27 • specifying whether only itself and the registrant have access to the listing
28 information, or whether some or all of the information held may be accessed by
29 others, e.g. purchasers of medical devices, while taking care to safeguard
30 commercially sensitive information;
- 31 • on a periodic basis, not more frequent than annually, requesting each registrant to
32 confirm that the information provided for medical device listing purposes
33 continues to be accurate.

35 **6.6 Role of the Registrant**

36 6.6.1 The registrant is required to:

- 37 • provide the RA with the medical device listing information specified in Section
38 6.4;
- 39 • attest to its accuracy;

- 1 • update the information provided within 30 calendar days of becoming aware of
2 the occurrence of any change, or when requested to do so by the RA, in order to
3 maintain the accuracy of the listing database;

4 **PUBLIC COMMENT IS REQUESTED ON THE FOLLOWING SUBJECT**
5 **– is this bullet required or is it sufficient for the registrant to provide information**
6 **on any changes annually?**

- 7 • respond to the RA’s request to confirm that the information provided for device
8 listing purposes continues to be accurate.