HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

June 2018

MEDICAL DEVICE GUIDANCE

GN-11: Guidance on the Declaration of Conformity

Revision 1.3

HSA
Health Sciences Authority

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PREFACE

R1.1 ►This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors. ◄

REVISION HISTORY

Guidance Version (Publish Date) *[3 latest revisions]*	Revision
GN-11: Revision 1 (November 2011)	R1
R1.1 ►GN-11: Revision 1.1 (April 2014)	R1.1
R1.2 ►GN-11: Revision 1.2 (01 November 2017)	R1.2
R1.3 ►GN-11: Revision 1.3 (01 June 2018)	R1.3

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

1. INTRODUCTION

1.1. Purpose

This document provides guidance to assist a product owner in the preparation of a Declaration of Conformity (DOC) to Singapore's regulatory requirements.

1.2. Background

One element of a global regulatory model for medical devices is that the product owner attests that its medical device complies fully with all applicable Essential Principles for Safety and Performance and draws up a written DOC.

1.3. Scope

This document is applicable to all medical devices that are to be supplied in Singapore.

1.4. Definition

Nil.

2. COMPONENTS OF A DECLARATION OF CONFORMITY

The DOC (see Annex 1) shall be in English and should contain the following information:-

- an attestation that each medical device that is subject to the declaration
  - complies with the applicable Essential Principles for Safety and Performance, and
  - has been classified according to the device classification rules;
- information sufficient to identify the device/s to which the DOC applies;
- the risk class allocated to the device/s after following the guidance found in Principles of Medical Device Classification;
- the date from which the DOC is valid;
- the name and address of the product owner;
- quality management standards;
- medical device standards (product standards[1]);
- the name, position and signature of the responsible person who has been authorised to complete the DOC upon the product owner's behalf.

R1.3 ►

The Essential Principles for Safety and Performance of medical devices is applicable for all medical devices, is in accordance with the Health Products (Medical Devices) Regulations 2010 and laid out in GN-16 Guidance on Essential Principles for Safety and Performance of Medical Devices. ◄

[1] Standards may include international (e.g. ISO, IEC), regional (e.g. CEN) and national (e.g. SS, ASTM, BS) standards.

3. WHO IS RESPONSIBLE FOR PREPARING THE DECLARATION OF CONFORMITY

The product owner of the medical device or a person authorised by the product owner is responsible for preparing and signing the DOC. The hardcopy of the DOC should be signed and dated. The signed and dated hardcopy should be scanned for submission as part of product registration. The original signed copy of the DOC should be made available to the Authority upon request.

ANNEX 1

DECLARATION OF CONFORMITY

[To be printed on Company Letterhead of Product Owner]

Name and Address of Product Owner:

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Manufacturing Site:

R1.1 ►*< Physical manufacturing site(s) including sterilization site(s) >* ◄

Medical Device(s):

< e.g. product name and model number>

Risk Classification: e.g. Class B, rule

R1.1 ►*< Risk Classification of medical device(s) according to the classification rule, and the rule(s) used to determine the classification>* ◄

Quality Management System Certificate:

< Certification Body and Certificate Number, issue date, expiry date>

*For **Class B, Class C and Class D medical devices**, declaration of conformity to either of the following QMS standards is mandatory:*

- *ISO 13485*
- *US FDA Quality System Regulations*
- *Japan MHLW Ordinance 169*

Standards Applied:

< International standards; OR Regional Standard; OR See Attached Schedule for multiple standards >

This declaration of conformity is valid from *<Day Month Year>*

Authorised Signatory:

Name, Position Date

HEALTH SCIENCES AUTHORITY

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Blood Services Group
Applied Sciences Group

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