Medtronic

27th February 2019

Medtronic's written submission in response to ICASA's Draft Conformity Assessment Framework for Equipment Authorization

[Government Gazette Number: 42108, Notice Number 1381 of 13 December 2018]

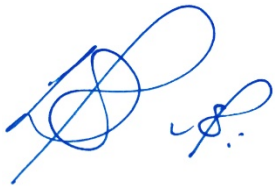
INTRODUCTION

As a global leader in medical technology, services and solutions, Medtronic improves the health and lives of millions of people each year. We believe our deep clinical, therapeutic and economic expertise can help address the complex challenges — such as rising costs, aging populations and the burden of chronic disease — faced by families and healthcare systems today. But we can't do it alone. That's why we're committed to partnering in new ways and developing powerful solutions that deliver better patient outcomes.
Founded in 1949 as a medical repair company, we're now among the world's largest medical technology, services and solutions companies, employing more than 85,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries. Join us in our commitment to take healthcare Further, Together. Learn more at Medtronic.com.

Medtronic (Pty) Ltd ("Medtronic") welcomes the opportunity to comment on the "Draft Conformity Assessment Framework for Equipment Authorization" as published by ICASA ("the Authority") in Government Gazette No. 42108, Notice Number 1381 of 13 December 2018.

Medtronic confirms its willingness to participate in any further consultative process, which the Authority may undertake in this regard.

Yours Sincerely



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LET'S TAKE HEALTHCARE
FURTHER, TOGETHER

Part A: In Principle Comments

MEDTRONIC congratulates the Authority on completing the substantial endeavour of drafting the changes with the intent of amending the Draft Conformity Assessment Framework for Equipment Authorization.

Part B: Comments on the Draft Conformity Assessment Framework for Equipment Authorization

MEDTRONIC thanks the Authority for the opportunity to comment on the draft conformity assessment framework for Equipment Authorization.

1.1 The Design of Conformity Assessment Scheme

A conformity assessment scheme (CAS) relates to the degree of risk associated with on-compliance considering aspects such as safety, health or environmental impact, durability, compatibility and suitability for intended use. When consequences are insignificant or not severe, society expects little or no demonstration of conformity of product since the problems generated can be easily addressed and resolved after they occur. In these cases, the supplier's claims may be sufficient, but they may be complemented by third-party product certification on a voluntary basis.

MEDTRONIC Comment

It is important that the safety aspects referred to relate to the safety of the radio link, and not safety of the product itself. For instance, patient health safety for medical devices is unrelated to the radio link, and subject to separate regulation through the Medicines and Related substances Act 101 of 1965, and the Hazardous substances Act 15 of 1973 where applicable.

1.2 Voluntary and Regulatory Schemes

verification *(in which case, the manufacturers test their own device)*;
declaration of conformity *(in which case, requires testing by an accredited test laboratory)*; or
certification (*in which case, is issued by the FCC or a designated Telecommunications Certification Body (TCB) based on test results submitted by the supplier*).

MEDTRONIC Comment

Verification and SDoC are now combined under the First Report and Order regulations of July 14 2017

Mark of Conformity

A mark of conformity relates to statements of conformity and may be associated with placing a mark of conformity on a product where conformance has been met.

MEDTRONIC Comment

MEDTRONIC would like to understand if the CE mark (or other international mark) would be accepted to support the Self-Declaration of Conformity?

Supplier Declaration of Conformity

The SDoC is the conformity assessment scheme used for low risk and mature products. The manufacturer/supplier that conscientiously undertake SDoC result in better conformity outcomes than independent third-party assessment. This is true if the manufacturer/supplier has invested in its internal quality control activities.

MEDTRONIC Comment

This would be very beneficial for Medtronic implementing internal production control, self-audits, CAPAs, etc. by certification through the Quality management system, ISO13485:2016

8. Proposed Conformity Assessment Approach

Question 1

In your view, what are the benefits of having conformity assessment to support the regulations?

MEDTRONIC Comment

MEDTRONIC supports manufacturer conformity assessments by the introduction of SDoC. It will benefit ICASA by reducing workload for type approval. It would bring more market access to the users in South Africa. There could also be an added benefit to the customs and excise department in that the workload there would also be reduced due to harmonisation.

8 Proposed Conformity Assessment Approach

Question 2

Do you see any benefits in risk profiling and the categorization of equipment in carrying out the conformity assessment?

MEDTRONIC Comment

This would also benefit ICASA in that the workload would be reduced for type approval. This is beneficial for Medtronic as many devices implement very low power short range telemetry that operate in license exempt bands. Co-existing studies have been conducted around the world showing that these low power short range telemetries operating in these licence exempt bands are compatible with other users in the band and therefore pose very low risk of harmful interference in the band. These short-range telemetry devices operate under non-protected non-interference basis. Medtronic recommends categorising such devices as low risk devices.

8 Proposed Conformity Assessment Approach

Question 4
Can you suggest an appropriate conformity assessment approach that can address the current Approval Framework challenges?

MEDTRONIC Comment
Medtronic suggests the manufacturer conformity assessment based on self-declaration. Also, a process for exceptional approval can be facilitated. Low-risk equipment should be able to be approved or exempted in cases where frequency bands or standards are not available or accepted, for the patients benefit.

8 Proposed Conformity Assessment Approach

Question 5
In South African context, what are the benefits for the Authority collaborating with other regulatory institutions/organizations/states?

MEDTRONIC Comment
The benefits of the authority collaborating with other regional and international regulatory institutions is the harmonisation and coordination of the conformity assessment process, market surveillance enforcement and spectrum management.

8.1 Supplier declaration of conformity

Proposed Approach
The Authority proposes allowing SDoCs to be one arm of its conformity assessment framework, specifically in terms of SDoC I as outlined Table 3 above.
SDoC I requires that:
1) the product be tested by an accredited test laboratory;
2) the test reports need to be retained by the supplier for a period to be stipulated by the Authority;
3) the supplier registers the declaration with the Authority as prescribed; and
4) the products that are the subject of the SDoC would need to be labelled/marked in line with the Authority's prescripts.
The SDoC must be registered with the Authority prior to the use, supply, sale, offer for sale, lease, and/or hire of electronic communications equipment that is subject to SDoC within the Republic of South Africa.

MEDTRONIC Comment

MEDTRONIC would like to understand what are these prescriptions defined by the Authority? Would CE mark or any other international type approval mark (FCC, ISED, etc) be acceptable? CE mark would be recommended, being also (mainly) a self-declaration scheme.

8.1 Supplier declaration of conformity

Proposed Approach

Question 6

Given table 3, which SDoC scheme/s would best suit the South African market, and why?

MEDTRONIC Comment

SDoC II, which puts the least strain on manufacturers. The hard copy of a SDoC shall be provided upon request to the end user.

8.2 Equipment Type Approval Exemption

Proposed Approach

Question 7

In your definition/understanding, what ICT equipment can be classified as low risk and may be considered for equipment authorization exemption?

MEDTRONIC Comment

In alignment with ITU regulations Medtronic believes that all SRD should be classified as low risk and considered for equipment authorisation exemption. Medical Devices are provided specifically to the healthcare professionals (hospitals) and therefore pose lower risk.

8.2 Equipment Type Approval Exemption

Proposed Approach

Question 8

What are the risks associated with exempting ICT equipment from Approval Framework, and how can they be mitigated or eliminated?

MEDTRONIC Comment

The risk is an increase of devices in the market with little or no control. If this exemption is risk based, it would be acceptable with risks being mitigated through market surveillance, regulation and associated activities, and the increased collaboration between the regulator and manufacturer.

8.3 Market Surveillance
Proposed Approach
Question 9
What would you propose the Authority do to effectively execute its responsibilities on market surveillance considering the current fiscal challenges?

MEDTRONIC Comment
MEDTRONIC agrees that the focus is put onto regulated market surveillance scheme as well as increased training on the scope of devices (e.g. Medical Devices) in the market.

8.3 Market Surveillance
Proposed Approach
Question 10
What are the prevalent equipment authorization challenges that may be experienced by manufacturers, distributors, suppliers and retailers post and pre-market surveillance?

MEDTRONIC Comment
MEDTRONIC believes that the biggest challenge lies in labelling, especially where model-specific approval numbers must be applied. Many devices are supplied sterile and any interference with packaging voids warranties. Labelling exemption guidelines should be applied.

Acceptance of international conformity marks to support the self-declaration would be helpful and will reduce high costs associated to labelling, which is in detriment of the manufacturers who may swap those costs by R&D investments.
Harmonisation with international standards as they become applicable also leads to faster approvals for the medical device industry and less workload for the Authority.

END