

# Response ID ANON-3NHQ-DDC7-V

Submitted to Proposed refinements to the regulation of personalised medical devices  
Submitted on 2021-07-06 12:20:55

## Introduction

1 What is your name?

Name:

[REDACTED]

2 What is your work title?

Work title:

[REDACTED]

3 What is your email address?

Email:

[REDACTED]

4 What is your company/organisation?

Organisation:

Queensland Health Professional Leaders in Occupational therapy/ MSHHS Occupational Therapy

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

Ipswich Road Woolloongabba

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:

Health service

7 Are you responding:

On behalf of an organisation

## Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

Yes

If you answered 'no' to the above question, why do you disagree with the rationale for the proposed exclusion of the products listed?:

9 Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

As these devices do not pose significant harm and are accessories and/or low risk medical devices, they will have low likelihood of injury that would require monitoring or oversight.

10 Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?

Ensure your answer directly addresses (1) why the products pose no, or insignificant, levels of risk or (2) why the product does not meet the definition of a medical device. :

Occupational Therapy (OT) made devices that are accessories of medical devices and help attach the device to the body to make it wearable. The device itself should be registered but the attachment manufactured separately (by OT) should be excluded as it alone does not constitute a medical device and is low risk.

Cosmetic/aesthetic splinting made by Occupational Therapists to cover/fill out defects from trauma/cancer i.e. shin defect – recreate leg contour under clothing, thumb amputation – thermoplastic insert into glove. Devices modify the external anatomy but do not diagnose, monitor, treat or alleviate the

disease or injury.

Adaptive aids and equipment that helps the user complete a task that may prevent, alleviate, treat an injury or illness but that the equipment or aid in itself does not. I.e. Dycem non stick matting is used so that a client can complete two handed scar massage with only one hand (dycem provides skin traction), dycem is provided not as a scar management (medical) device but as a means to enable the client complete self massage.

## Exemption

11 Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in the consultation paper?

Yes

If you answered 'no' to the above question, please explain why it is that you disagree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched medical devices?:

However do not agree with the Professions listed – ie Prosthetics and Orthotics only. This should include all AHPRA registered health professionals that are trained and responsible for manufacturing exempt orthoses and prosthesis including Occupational Therapists and Physiotherapists.

12 Can the risks posed by Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in the consultation paper be adequately managed if they are exempted from inclusion in the ARTG?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

Yes, the following mechanisms allow for adequate monitoring and reporting of manufacturers in this field and ensure that class 1 non-sterile, non-measuring patient-matched medical devices can be adequately managed should they be exempt from inclusion.

AHPRA registration: all Practicing QLD Health Occupational Therapists and Physiotherapists must be AHPRA registered and as such have oversight of minimum standard of education, continuing professional development and regulating standards.

QLD health employees work within the NSQHS standards as an accredited organisation and Queensland Health is regularly audited according to these standards.

QLD health employees work within a supervision framework that enables professional and clinical support appropriate to level of expertise.

RiskMan reporting is available across QHealth sites and provides a single state-wide integrated information system to collect, integrate, manage and report clinical incidents, workplace incidents, consumer feedback and risk.

Policies, Procedures and Work Unit Guidelines exist across QHealth Occupational Therapy Departments to ensure safe and consistent clinical practice.

Clinicians in areas of higher clinical/technical skill development are encouraged to hold membership with the appropriate national body and access training and ongoing CPD i.e. Australian Hand therapy Association (AHTA), Australian and New Zealand Burns Association (ANZBA), Australasian Lymphology Association (ALA) and National Lymphoedema Practitioners Register (NLPR).

Onsite competency training and supervision.

QHealth mentorship and support through following state-wide groups i.e. Plastics Collaborative and Special Interest group, Queensland Hand therapy Network (QHTN), and the State-wide Lymphoedema Network.

Patient risk from the suggested examples of exempt medical devices that OT manufacture i.e. Hand splints (with or without outrigger); Shoulder orthosis AND

Ankle-foot orthosis most commonly relate to skin issues ie skin irritation, minor pressure areas, general discomfort, localised oedema and/or altered sensation and are generally temporary in nature. These risks are outlined in splint instruction handouts provided at point of care and patients/carer are encouraged to contact therapist as soon as they occur for adjustment and further prevention.

RiskMans are completed for actual and "near miss" incidents.

13 Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?

Ensure your answer directly addresses the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.:

Yes

All splinting of the body (non-invasive) abides by the same principles outlined above and as such, these should also be exempt. I.e. knee splinting to protect muscle flap, neck splinting for burns contracture prevention etc.

Scar management is a significant area of practice for Occupational Therapists and as part of this, a combination on ARTG manufactured devices e.g. cica care silicone and Ottoform are used along with patient-matched splinting, massage and interim compression devices to secure in place and provide external pressure to physiologically change the scar process. As Occupational Therapists we are trained in Scar development and management and principles of oedema management and compression. We attain the splinting and compression skill development in our training and again in on the job training and attendance at special interest groups, conference and workshops and membership of national bodies. Where able, devices registered on the ARTG are utilised in this space however where not available or the patient needs are not standard, devices are manufactured.

As above, main risks reported are skin irritation, minor pressure areas or oedema. These are registered on RiskMan and Patient information is provided at point of care on monitoring for these issues.

#### Compression management

Whilst we rely on external agencies to manufacture high grade compression that is listed on the ARTG, patients often require interim garments, pressure inserts or low-level compression over wound dressings and for initial wound, scar and oedema management. These are manufactured according to core oedema management principles taught at university and a combination of on the job training, workplace competencies, courses and conferences.

As these provide low level compression, risk is low and reported via RiskMan. Patient information is provided at point of care to monitor for these issues.

#### Weighted Devices

Weighted devices are used in mental health Services to create a physiologically calming response for patients. These devices are commercially available for the general population, however can be modified to meet the specific needs of the user and/or be custom made/patient matched accordingly to encourage use – i.e. weighted bunny toy for child with mental health issues. When used in acute care settings, competency training and work unit guidelines on use are completed to ensure safe use. These are low risk items with systems in place to facilitate safe use and monitoring.

#### Positioning Devices

Similarly to splinting, Occupational Therapists use splinting and foam etc to provide optimal positioning to help align posture and prevent pressure/pain to areas i.e. foot drop splints for the lower limb to prevent shortening of the achilles tendon, cushions with cut out post radiation to buttocks region or foam support within car seats to ensure appropriate hip angle for children in hip spica casts. The same principles apply to splinting and pressure care and Patient information is provided at point of care and any risks reported.

Please note this is just a summary of the areas in which OTs work and manufacture. Our profession and training provide us with the clinical reasoning to help people with different needs adapt to standard environments and a lot of our work involves modifying standard pieces of equipment to allow access and use. All the examples of items we manufacture have been deemed class I low risk and with the outlined risk management strategies in place are well regulated.

The risk of patient harm associated with lack of regulation versus the loss of professional artistry and patient access to customised care needs to be considered

#### Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper?

Not Answered

If you answered 'no' to the above question, please explain why you disagree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices?:

15 Do you agree that the risks associated with the Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure?

Not Answered

Please explain your response, including by providing examples that illustrate and/or support your position.:

16 Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate?

Please ensure that your answer directly addresses what measures are in place to manage the risks associated with the devices.:

17 Are there any Class IIa patient-matched medical devices that should not be subject to an alternative conformity assessment procedure? What are they, and why not?

Please outline your reasoning.:

#### Alternative approaches we should consider

18 Are there alternative mechanisms for minimising the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?

If applicable, please write your response in the text box below.:

Reliance on current already known and tested mechanisms such as NSQHS and Riskman incident reporting along with registration through national bodies ie AHPRA

#### Required final step - Publishing my response

19 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent

20 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, without my name but including my organisation's name

21 If there are specific answers you have provided that you do not wish to be published, please indicate these below.

Please state below any specific questions that you do not wish to have your answers to published.:

NIL

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

23 By making a submission, I acknowledge that:

I acknowledge the above