Australian Government
Department of Health

**Deputy Secretary**

Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk-OBPR@pmc.gov.au

Dear Mr Lange

**Certification of independent review: Review of Medicines and Medical Devices Regulation**

I am writing to certify that the attached independent review of the Therapeutic Goods Administration's regulation of medicines and medical devices has undertaken a process and analysis equivalent to a Regulation Impact Statement (RIS).

I certify that this document adequately addresses all seven RIS questions, and is submitted to the Office of Best Practice Regulation for the purposes of introducing a power in the *Therapeutic Goods Act 1989* to allow the making of regulations to provide for an Australian unique medical device identifier (UDI).

Specifically, the independent review (pg 128 of Stage 1 report) confirmed that "introducing this requirement (ie: for an UDI)…. at the beginning of the regulatory process will not present an additional Australian regulatory burden".

I am satisfied that the scope of the problem and the recommendations identified in the certified review including Recommendation 20 – the regulation of medical devices by the Australia National Regulatory Authority is, wherever possible, aligned with the European Union Framework (OBPR Reference 24696)) are substantially the same as the identified problem and recommendations in the policy proposal.

I note that the implementation of this proposal will not increase the regulatory burden to business, community organisations or individuals due to the adoption of the UDI being a global requirement of countries from where the majority of medical devices are manufactured and imported for supply in Australia.

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Accordingly, I am satisfied that the attached report is consistent with the *Australian Government Guide to Regulatory Impact Analysis*.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

05 June 2020