[redacted]

From: [redacted]
Sent: Wednesday, 26 July 2023 4:03 PM
To: Device Reforms
Cc: [redacted]
Subject: Public consultation - Proposed application audit framework for medical devices

With regard to the above consultation:
INKA underwent MDR Audit in March 2023 successfully.

Having gained the experience in creating the required documentation, the level of approvals and compliances that are required and the cost burden involved we would
Request that TGA consider any manufacturer of reusable medical devices who holds MDR certification as being compliant and exclude them from audits.
MDR requires annual audit, post initial certification, so the ongoing compliance is monitored and measured.
This applies to all aspects (ie PMS, RM etc) of MDR.

We look forward to TGA's decision

Kind regards,

[redacted]

Kind Regards,

[redacted]

INKA™
SURGICAL INSTRUMENTS

116 Cutler Road, Jandakot WA 6164 Australia
m. [redacted] I t. [redacted] I freecall. 1800 756 757
e. [redacted] I w. www.inkasurgical.com.au