



South Asia

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TÜV SÜD South Asia ● TÜV SÜD House ● Off Saki Vihar Road, Saki Naka ● Andheri (East) ● Mumbai - 400072

Date: - 7th July 2020

To our Most Valuable Customers:

INFORMATION ABOUT TRANSITION FOR ICMED FROM ISSUE 1 to ISSUE 2

This letter is a part of our ongoing commitment to keep you informed of changes that could affect your Indian Certification of Medical Devices ICMED (Scheme) certification. These changes will affect you if you currently have or/are working towards related TÜV SÜD management system certification.

As per the policies of ICMED Transition Policy shared by QCI, we must ensure that all certified companies / clients get upgraded to new standard within the mandatory transition period stated below. This demands to have the transition plan of certification body related to existing certificates and upgrade to new applicable standards for each certificate issued.

We kindly request you to note the below –

- Few recently released certificates (based on ICMED ISSUE1) may have validity beyond 2020-12-31. With the transition policy, all such certificates now are VALID until 2020-12-31. Any certifications to ICMED scheme Certified client will be automatically gets terminated at the end of the transition period by 2020-12-31. To restore the certification after 2020-12-31. as per New ISSUE 2 for ICEDM 9000 & ICMED 13485 Scheme's, client must undergo stage1 & stage 2 audit.
- TÜV SUD shall conduct transition audit during routine surveillance, recertification or a special audit. This routine transition audits will be a single visit audit.
- Where transition audits will be carried out in conjunction with scheduled surveillance or recertification then **0.5 man-day** will be applied in addition to routine man-day calculation to cover existing and new requirement implied by ICMED ISSUE 2 dtd:- JAN 2019
- In case of Special audits (in between regular surveillance or recertification / immediate after recently completed audits) **One Man-day special audit** shall be conducted to cover the new requirements.
- For all currently certified clients – Transition audit shall be completed until 2020-12-31.
- For all new clients – all certification audits shall be conducted as per New version only.
- All audits (currently certified and new clients) shall only be against the new Standard ISSUE 2 for ICMED scheme from 06-09-2020

We here by request you to get in touch with our local branch and understand the process in detail.

Thank you for your attention and supporting in Transition.

TUV SUD South Asia,
Team Certification Body

PAN No.: AABCT0716G
TAN No.: MUMT09385F
Maharashtra GSTIN :
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Registered Office
TÜV SÜD South Asia Pvt. Ltd.
TÜV SÜD House
Off Saki Vihar Road
Saki Naka, Andheri (East),
Mumbai – 400072. India

Corporate Office:
TÜV SÜD South Asia Pvt. Ltd.
Solitaire, 4th Floor,
ITI Road, Aundh,
Pune – 411007, India.

Email: info@tuv-sud.in
www.tuv-sud.in

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