Objectives and limitations: In-country Lab Testing

- Would TÜV can be help of those limitation or Challenges?

December 5, 2017

TÜV Rheinland Japan Ltd.
Junya Onae
Manager, BS-Products, Medical
Asia Pacific Region

TÜV Rheinland India PVT Ltd.
Basavaraj Angadi
Assistant General Manager,
BS-Products

TÜVRheinland®
Precisely Right.

Wherever you are, we are with you.

Since 1872, we strive to improve Safety and Quality of Products, Systems, and People.

19,630 Employees

114 Operating companies **500** Locations

> 200 Labs

66 Countries

37 Industries **2,500** Services

Headquarter:
Cologne,
Germany

TÜVRheinland®
CERTIFIED

TÜVRheinland®
Precisely Right.

TÜV Rheinland, Conformity Assessment Body for Medical Devices

Major Conformity Assessment Services

- EU Notified Body under MDD, IVDD, AIMD
- ISO 13485 – QMS certification under CMDCAS and other local accreditations
- CAB under MDR, Malaysia
- AO under MDSAP
- RCB under PMD Act, Japan
- Medical Device Testing with IEC/ISO/EN/AMMI/CSA
- NRTL, US: cTUVus, cTUV, TUVus

TÜVRheinland®
Precisely Right.

Objectives and limitations: In-country Lab Testing

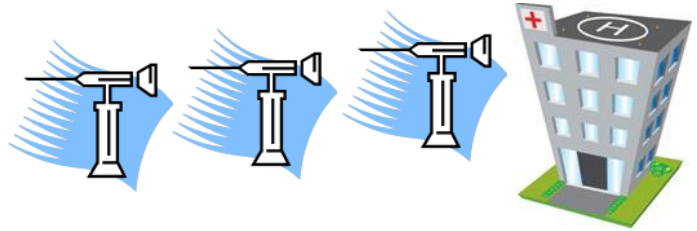
What would be the objectives for In-country Lab Testing?

TÜVRheinland®
Precisely Right.

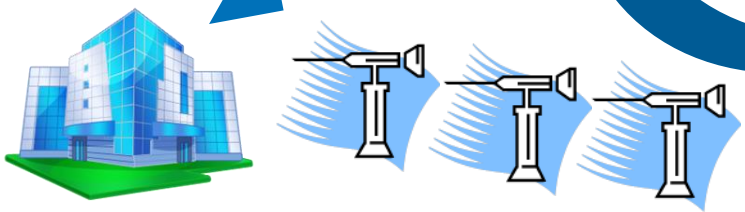
Objectives and limitations: In-country Lab Testing

Objective would be split into 2 key aspects:

- ☑ **"Safeguard for Public Health"**



- ☑ **"Developing Medical Device industry sector"**



TÜVRheinland®
Precisely Right.

Objectives and limitations: In-country Lab Testing

Possible targets with each objective could be as follows.

Safeguard for Public Health

by supporting Test data in :

- Pre-market approval
- Post-market surveillance

Developing Medical Device Industry sector

by supporting:

- Incubation of SMEs
- Innovation of Technology

TÜVRheinland®
Precisely Right.

Objectives and limitations: In-country Lab Testing

So easy to say……

but

Any Limitation or Challenges?

TÜVRheinland®
Precisely Right.

Objectives and limitations: In-country Lab Testing

Yes, there would be major limitations and challenges.

Competence & Capacity

Budget

ROI

TÜVRheinland®
Precisely Right.

Objectives and limitations: In-country Lab Testing

Would TÜV can be help of those limitation or Challenges?

TÜVRheinland®
Precisely Right.

Yes, external lab. like us, TÜV Rheinland can support in overcoming those limitation or challenges.

Objectives and limitations: In-country Lab Testing

福島県

TÜVRheinland CERTIFIED

http://www.pref.fukushima.lg.jp/site/portal-english/ps-fmddsc-1.html

Since 2016, TÜV Rheinland Japan supports the Public lab on MoU.

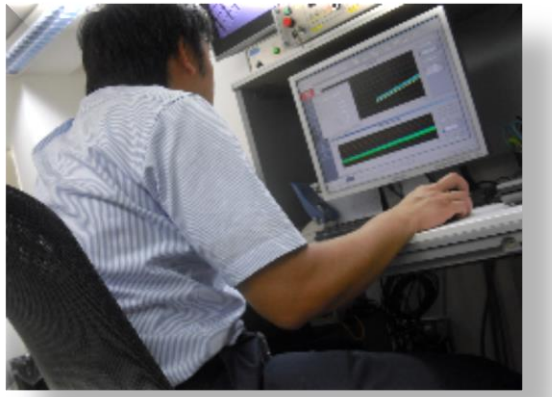
TÜVRheinland®
Precisely Right.

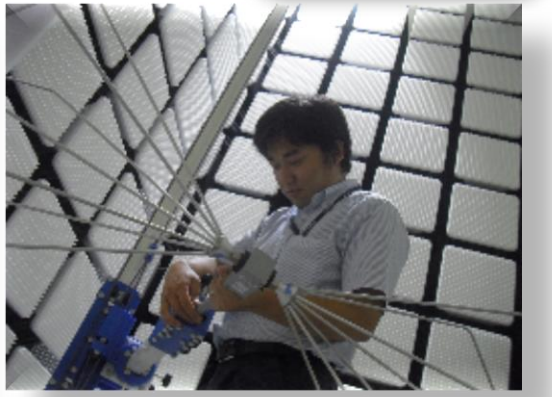
We cooperate with the lab, for instance, by:

- TÜV Rheinland Experts provide advanced training for staffs using the test facility in the "Fukushima Medical Device Development Support Centre.“
- TÜV Rheinland Experts provide “public seminars” related to Medical Device Conformity Assessments.
- TÜV Rheinland Experts provide comprehensive support to manufacturers for “their international business success”.

Objectives and limitations: In-country Lab Testing

“Hands-on-support” by TÜV Rheinland





TÜVRheinland®
Precisely Right.

Another example, in Korea

TÜV Rheinland Korea and Gwangju Technopark Sign an MOU on Healthcare Robots

2017/03/30Korea

- **TÜV Rheinland Korea signed an agreement on March 16th with Gwangju Technopark for mutual business cooperation in the healthcare robot industry.**

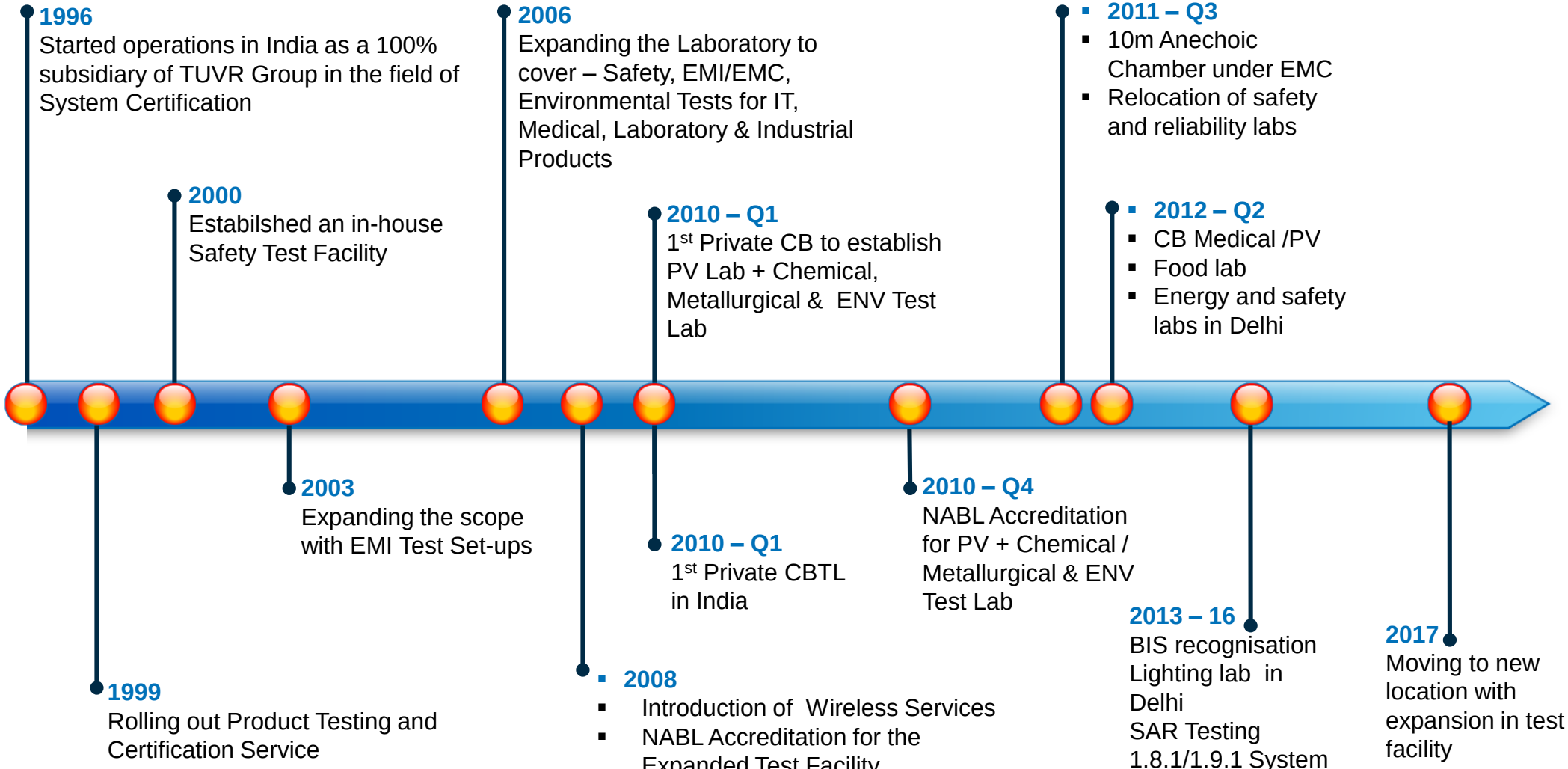
- **Both parties agreed to establish an official system of cooperation, which will in turn facilitate the correspondence of experiences necessary to construct a healthcare robot test bed at Gwangju Technopark, and galvanize the exchange of information on certification and evaluation as well as human resources for the development of professional technology.**

- **“In light of this MOU, TÜV Rheinland Korea will actively cooperate for the successful completion of the Gwangju Technopark healthcare robot test bed, and reinvigorate efforts to advance the healthcare industry through an exchange of professional labor force and technological information,” says Carsten Lienemann, CEO of TÜV Rheinland Korea.**

Medical Device Testing & Certification

TÜVRheinland®
Precisely Right.

TÜV Rheinland India – 20 Years of Existence.



TÜVRheinland®
Precisely Right.

Medical Devices Testing and Certification - Services

Comprehensive test facility to test & certify medical devices for various country requirements.

Radiation test facility for x-ray systems, C-Arm systems etc.

Test facility includes medical safety as per IEC/EN/UL 60601 – 1 & -2-XX for product specific standard series. E.g. Infant care, Imaging, Diagnosis, Therapeutic devices etc.

Test facility also includes , exclusive EMI / EMC & Wireless / IoT facility and Reliability testing

QMS: ISO 13485:2016 for New MDR India

ICMED : 13485 (NABCB)

CE mark certification as per MDD, IVD

TÜVRheinland®
Precisely Right.

Medical Devices Testing and Certification - Facilities

- 10m Anechoic chamber to perform complete testing & certification activities to meet global requirements
- Medical safety & reliability test facility as IEC & ASTM standards
- Lead room facility to offer radiation testing for X- Ray equipment
- Exclusive EMI / EMC test facility as per IEC 60601 -1-2, covering 3rd & 4th edition
- Exclusive Wireless / IoT test facility to offer global market requirements for medical devices

TÜVRheinland®
Precisely Right.

Test Facilities

Medical Safety and Reliability Services

Medical Safety Tests : IEC/EN 60601-1 3.1 edition and Particular standards

Fire / Heat Testing

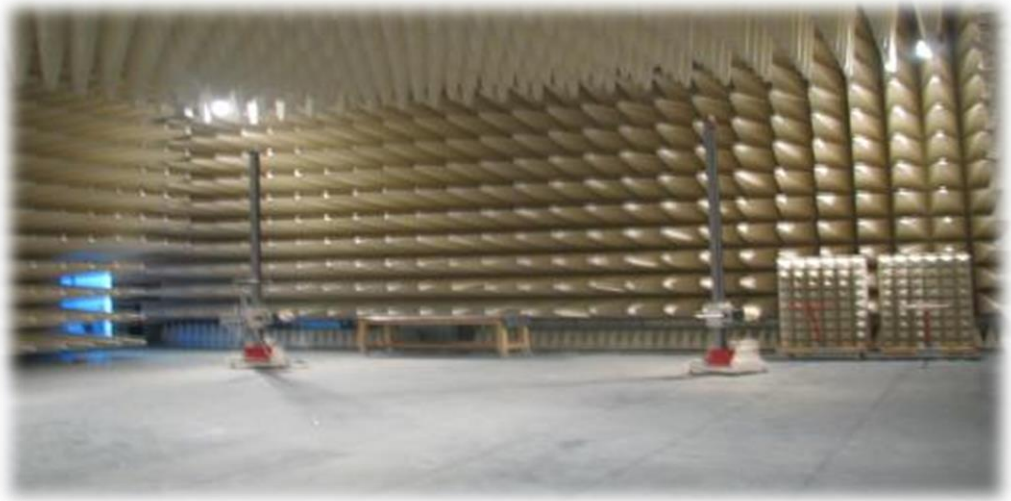
Mechanical Tests

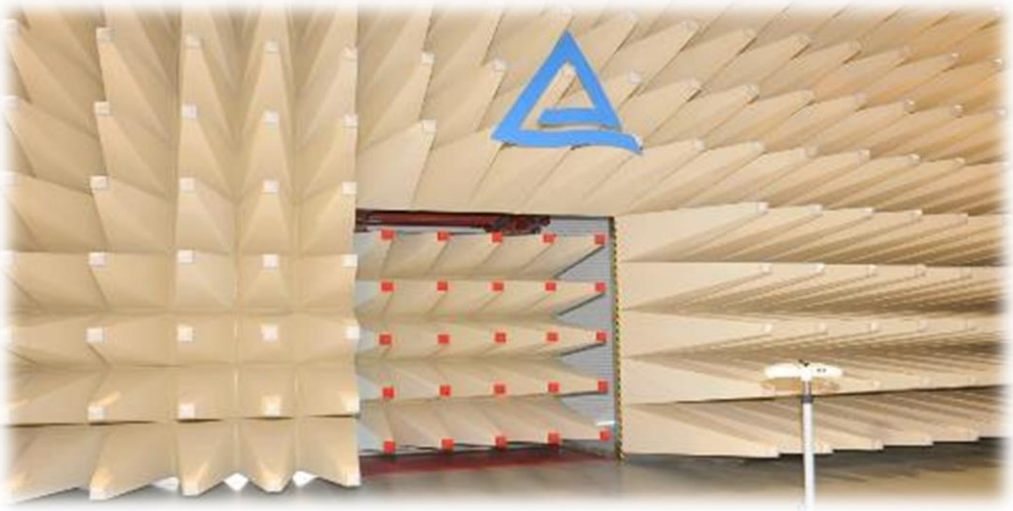
Safety

EMI / EMC and Wireless / IoT Facillities

Accredited in-house laboratory to perform 60601-1-2 :3rd , 4th edition EMI/EMC testing and Wireless / IoT testing with multi-country approvals

10m Anechoic Chamber





Specific Absorption Rate (SAR)

TÜVRheinland®
Precisely Right.

Market Access Services

One report good for many countries → One stop shopping

Testing

Approval

CE ,FDA , NRTL , InMetro , CB & Others

Anatel / Inmetro / Brazil

CE / Europe

CE 0197

FCC / FDA / US

And Many Many More

NRTL / US & Canada

Multiple approvals based on one test Report

Our Accreditations – National and International

- TUV Rheinland India is one among the CBTL under NCB - TUV Rheinland Japan for Medical Device testing and certification.
- TUV Rheinland India lab accredited by NABL as per ISO 17025: 2005.
- TUV Rheinland India also has international accreditation from APLAC and ILAC.
- TUV Rheinland India is also recognized by NRTL, North America.


National Accreditation Board for Testing and Calibration Laboratories
(A Constituent Board of Quality Council of India)

CERTIFICATE OF ACCREDITATION

TUV RHEINLAND (INDIA) PRIVATE LIMITED

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2005

"General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

#82A, West Wing, 3rd Main Road, Electronics City, Phase-1, Bangalore, Karnataka

in the field of

TESTING

Certificate Number TC-5688 (in lieu of T-1849, T-2542, T-1543 & T-2571)

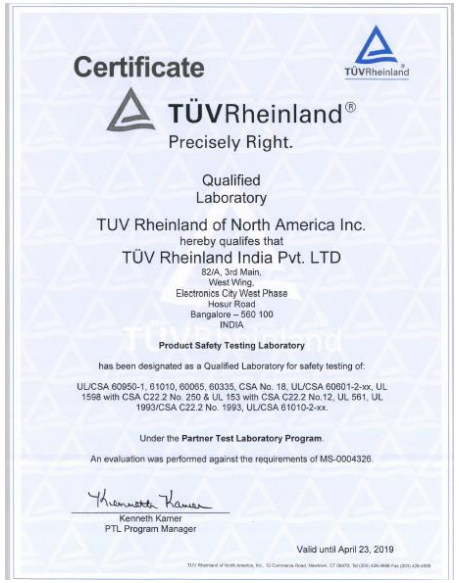
Issue Date 24/04/2017 Valid Until 23/04/2019

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

Signed for and on behalf of NABL

N. Venkateswaran
Program Director

Anil Relia
Chief Executive Officer


Certificate

TÜVRheinland®
Precisely Right.

Qualified
Laboratory

TUV Rheinland of North America Inc.
hereby qualifes that
TÜV Rheinland India Pvt. LTD
82/A, 3rd Main,
West Wing,
Electronics City West Phase
Hosur Road
Bangalore – 560 100
INDIA

Product Safety Testing Laboratory

has been designated as a Qualified Laboratory for safety testing of:

UL/CSA 60950-1, 61010, 60065, 60335, CSA No. 18, UL/CSA 60601-2-xx, UL 1598 with CSA C22.2 No. 250 & UL 153 with CSA C22.2 No.12, UL 561, UL 1993/CSA C22.2 No. 1993, UL/CSA 61010-2-xx.

Under the Partner Test Laboratory Program.

An evaluation was performed against the requirements of MS-0004326.

Kenneth Kamer
PTL Program Manager

Valid until April 23, 2019


International Electrotechnical Commission

IEC IECEE

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE)

CERTIFICATE OF ACCEPTANCE

TO PARTICIPATE IN THE IECEE CB-SCHEME

TUV Rheinland (India) Pvt. Ltd.

82/A, West Wing, 3rd Main Road, Electronics City Phase 1, Bangalore-560100, INDIA.

has been assessed and determined to fully comply with the requirements of ISO/IEC 17025: 2005-05, The Basic Rules, IECEE 01: 2014-11 and Rules of Procedure IECEE 02: 2015-06, and the relevant IECEE CB-Scheme Operational Documents.

TUV Rheinland (India) Pvt. Ltd.

is therefore entitled to operate as a CB Testing Laboratory under the responsibility of TUV RH Japan as National Certification Body and to carry out testing within the IECEE CB Scheme for the Scope (Product Category(ies) and Standard(s)) as listed in the relevant part of the IECEE Web Site at www.iecee.org, and is subject to all other terms as set forth in the IECEE Basic Rules and Rules of Procedure

This certificate remains valid until February 20th 2018 at which time it will be reissued by the IECEE Executive Secretary upon successful completion of the normally scheduled 3-year Reassessment Programme administered by the IECEE CB Scheme.

Signed by:

Kerry McMANAMA
IECEE EXECUTIVE SECRETARY AND COO

Date of Issue: 2016-07-21
TL332

APLAC
Asia Pacific Laboratory Accreditation Cooperation

ilac

TÜVRheinland®
Precisely Right.

Our Accreditations – National and International

The Federal Communications Commission (FCC), USA recently released DA-17-274A1 (released as on March 23, 2017). The document details the expansion of A2LA's current FCC scope of recognition to include accreditation of testing laboratories located in non-MRA countries, which includes labs in the India ,People's Republic of China, Philippines, and Thailand..

TÜV Rheinland India, is the first laboratory in India to be recognised by A2LA, USA & listed by Federal Communications Commission (FCC), USA – to perform EMI/EMC & Wireless testing and certification services locally in India according to various FCC standards for North American market.

Certificate Number: 4271.01

TÜVRheinland®
Precisely Right.

NABCB accredation

NABCB accredation on MDQMS 13485,ICMED 13485 and ICMED 9000 certification

National Accreditation Board for Certification Bodies

NABCB

QMS

ACCREDITATION CERTIFICATE

NABCB hereby confirms that

TUV Rheinland (India) Pvt. Ltd.

Operating from their office at

82/A, 3rd Main, West Wing,
Electronic City, West Phase (Phase I),
Bangalore – 560 100, India

complies to NABCB criteria (ISO/IEC 17021-1:2015
and ISO/IEC TS 17021-3:2013)
and is accredited to carry out

Quality Management Systems Certification

In accordance with the standards detailed in the accompanying Schedules

The Scope of Accreditation is described in the
accompanying schedule

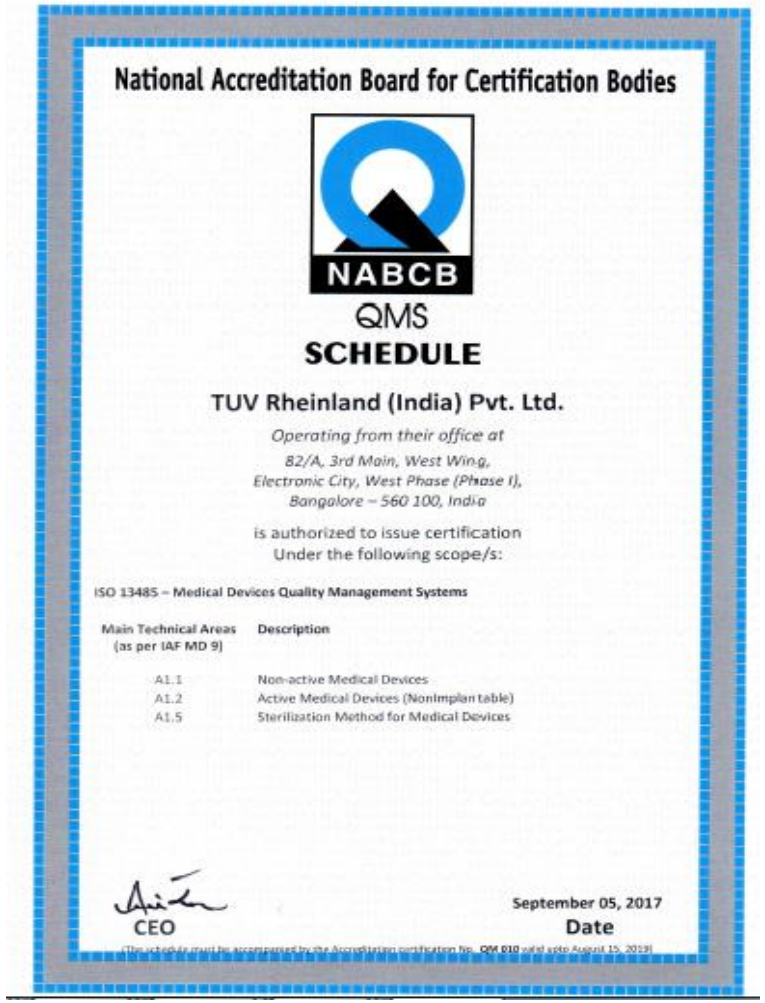
Date of initial accreditation	:	August 16, 2004
1st renewal	:	August 16, 2007
2nd renewal	:	August 16, 2011
3rd renewal	:	August 16, 2015
Validity of Accreditation	:	August 15, 2019

CEO

QM 010 — Certificate No.

September 05, 2017 — Date

(Please refer www.qcin.org/nabcb for validity of the certificate or contact CEO, NABCB for any related queries)



National Accreditation Board for Certification Bodies

NABCB

QMS

SCHEDULE

TUV Rheinland (India) Pvt. Ltd.

Operating from their office at

82/A, 3rd Main, West Wing,
Electronic City, West Phase (Phase I),
Bangalore – 560 100, India

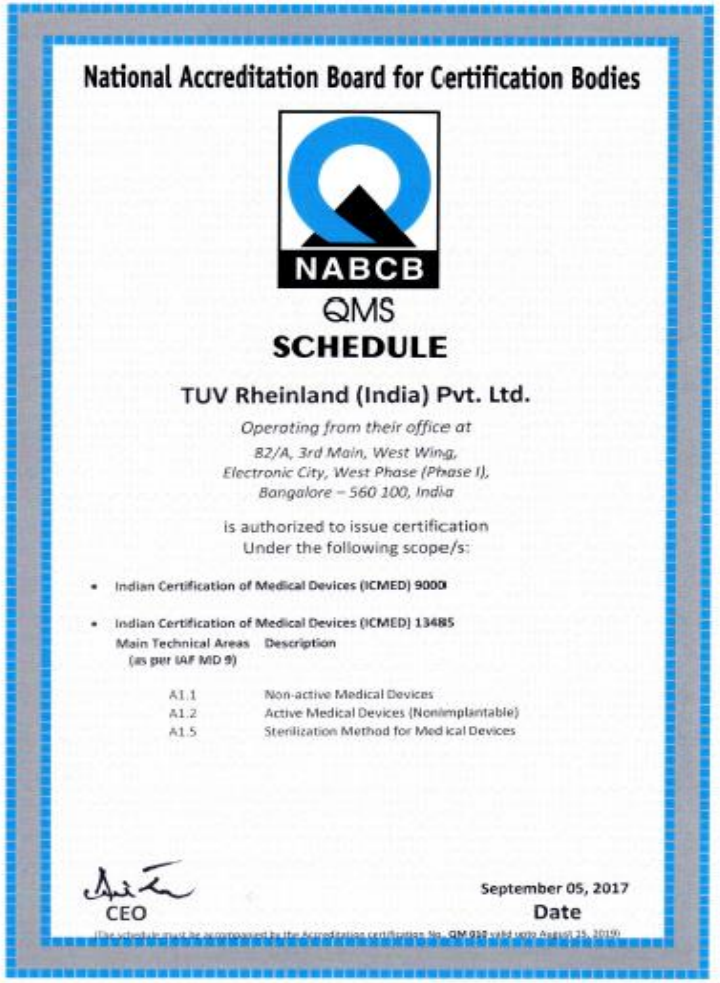
is authorized to issue certification
Under the following scope/s:

ISO 13485 – Medical Devices Quality Management Systems

Main Technical Areas (as per IAF MD 9)	Description
A1.1	Non-active Medical Devices
A1.2	Active Medical Devices (Nonimplantable)
A1.5	Sterilization Method for Medical Devices

CEO

September 05, 2017 — Date



National Accreditation Board for Certification Bodies

NABCB

QMS

SCHEDULE

TUV Rheinland (India) Pvt. Ltd.

Operating from their office at

82/A, 3rd Main, West Wing,
Electronic City, West Phase (Phase I),
Bangalore – 560 100, India

is authorized to issue certification
Under the following scope/s:

- **Indian Certification of Medical Devices (ICMED) 9000**
- **Indian Certification of Medical Devices (ICMED) 13485**

Main Technical Areas (as per IAF MD 9)	Description
A1.1	Non-active Medical Devices
A1.2	Active Medical Devices (Nonimplantable)
A1.5	Sterilization Method for Medical Devices

CEO

September 05, 2017 — Date

TÜVRheinland®
Precisely Right.

TUV Rhineland's Presence in AMTZ – Upcoming Project

- Andhra Pradesh MedTech Zone (AMTZ) Vishakhapatnam ,is an Indian Integrated Medical Device Manufacturing park
- TUV Rheinland has partnered with AMTZ to setup Testing Laboratory :

EMI/EMC Lab

Medical Safety Lab

Biomaterial Lab

TÜVRheinland®
Precisely Right.

Thank you.

TÜVRheinland®
Precisely Right.