QAI
Change Adapt Improve

QAI E-TALK

DATE - 7TH MAY 2020

TIME - 12-1pm IST

Beware of Substandard PPEs-Verifying Authenticity of Certificates

Speaker:

Mr. Anil Jauhri

Former CEO NABCB and International Expert on Accreditation System

Moderator:

Dr. B. K Rana CEO, QAI

To Join : https://us02web.zoom.us/meeting/register/tZYvceugqzMpGNBJY7f8_8aWHAKHIZq5RiyY

For any query contact: +91 9899548050

PPEs - RISK OF UNAUTHENTIC CERTIFICATION

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INTRODUCTION

- Personal Protective Equipment (PPEs) currently in focus – both quality and quality
- Ministry of Health issued **Guidelines for Rational Use of PPEs** in Mar, 2020
- Contain specifications for PPEs vide Annexure A
- Cover Gloves, Coveralls, Goggles, N95 Masks, Shoe Covers, Face Shields, Triple Layer Medical Masks, Body Bags – prescribe ANSI/ASTM/EN/ISO standards/EC regulations except Medical Mask – BIS stds or equivalent
- Prescribes certificate of analysis from national/ international organizations/labs indicating conformity to standards

PROBLEM

- Implied that ISO/USFDA/CE certificates acceptable
- Led to spurt of certificates in the market – not only in India but world over
- PPEs currently not regulated in India – said to be covered in definition of medical devices notified effective 1 Apr 2020 – 18 months time given for voluntary registration before compliance to Medical Devices Rules, 2017 is compulsory
- How to assure quality – producing a certificate for compliance to ISO/EN/ASTM standards or CE certificate the easiest option – since freely available in the market

VOLUNTARY CERTIFICATION

- For a variety of reasons – competition, desire to demonstrate higher quality etc – many voluntary standards and certifications in the market
- Some initiated by govt or govt institutions – ICMED scheme for medical devices of QCI-AIMED, ISI mark by BIS
- Several certifications granted by private certification bodies - ISO 9001, ISO 13485, WHO GMP, CE Mark (although a regulatory mark in Europe)
- Are these authentic??? Let us see

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 25th, 2020

Certificate of Compliance

No. 0B200331.ZUDDC53

Certificate's Holder: Zhejiang Ugly Duck Industry Co., Ltd.
No. 2 Dongfang South Road, Ouhai District,
Wenzhou City, Zhejiang Province, China.

Certification ECM Mark: Type Approved ®

Product: Medical protective clothing

Model(s): 2020313

Verification to: Standard:
EN 14126:2003
related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark; the conformity mark above can be affixed on the products according to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products, RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 31 March 2020

Expiry date: 30 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it www.entecerma.it

■ CERTIFICATE ■ CERTIFICADO ■ CERTIFICATO ■ ZERTIFIKAT ■ شهادة

Certificate of Compliance

This is to certify that

4WAY CLINIC AND CONSULTANCY

REGISTERED ADDRESS: 203 B, CARRARA BUILDING, HIRANANDANI ESTATE, THANE WEST – 400607, MAHARASHTRA (INDIA)

Has been assessed by QCS and found to be Comply with the requirements of:

ISO 16603:2004

"Clothing For Protection Against Contact With Blood And Body Fluids - Determination Of The Resistance Of Protective Clothing Materials To Penetration By Blood And Body Fluids – Test Method Using Synthetic Blood"

For the following scope:

"PERSONAL PROTECTIVE EQUIPMENT (PPE KIT), COVID – 19 TEST KIT, 3 PLY FACE MASK & N 95 FACE MASK"

Certificate Number: QCS-2020-WCAY-07173

To verify this certificate please visit at www.gacb.us

Date of Certification: 07th Apr 2020
Date of Recertification: 06th Apr 2023
(Subject to the company maintaining its system To the required standard)

1ST Surveillance Due: 06th Apr 2021
2ND Surveillance Due: 06th Apr 2022

GLOBAL ACCREDITATION CERTIFICATION BOARD GACB

Authorized Signatory

QCS

Validity of this Certificate is subject to Annual Surveillance audits done successfully

This certificate remains the property of QCS and must be returned whenever demanded QCS is an independent system product and personal assessment body QCS is accredited by

Global Accreditation Certification Board (GACB)
US OFFICE: Maryland Avenue, SW Washington, D.C. -20202
info@qcscertgroup.com, www.qcscertgroup.com

Certificate

We hereby declare that the technical file of product complied with the requirement of directives Medical Device Directive 2007/47/EC & Personal Protective Equipment Directive 89/686/EEC

Certificate no. CE-SLIL-20-142513

Manufacture
Name
Address

[redacted]

Product : **PERSONAL PROTECTION EQUIPMENT, DISPOSABLE BED SHEETS, DISPOSABLE ITEMS, SURGEON CAP, BOUFFENT CAP MASK, APRON, SHOE COVER, SURGICAL MEDICAL KITS, SANITARY NAPKIN, UNDERPAD, DRAPES, PATIENT I.D., BANDS SURGEON GOWN AND GLOVES (EXAMINATION GLOVES, SURGICAL GLOVES) SAFETY GOOGLES & FACE SHIELD**

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives Medical Device Directive 2007/47/EC & Personal Protective Equipment Directive 89/686/EEC

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity isconditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.gaafs.us

Date of Certification	**19TH March 2020**
1st Surveillance Due	**18TH March 2021**
2nd Surveillance Due	**18TH March 2022**
Certificate Expiry (Subject to the company maintaining its system To the required standard)	**18TH March 2023**

CE

Authorized Signatory

Validity of this Certificate is subject to annual Surveillance audits done successfully

This Certificate remains the Property of IMC Certification and must be returned if Certificate is Withdrawn
The Verification mail is : info@imccertification.co.in
IMC Certifications is Accredited by Global Accreditation Assessment Forum Series (GAAFS)

CERTIFICATE ■ CERTIFICADO ■ CERTIFICATO ■ ZERTIFIKAT ■ شهادة

ISSUES WITH CERTIFICATES

- Do we know who the certification body is – is it authentic – ECM in Italy, QCS in USA, IMC no location mentioned
- Two of them QCS and IMC claim accreditation – GACB and GAAFS – who are they – where are they – no mention
- Two of the certificates have CE mark
- How do we know these are authentic certificates
- **All certificates are unauthentic** – means you can not authenticate them through an independent 3rd party

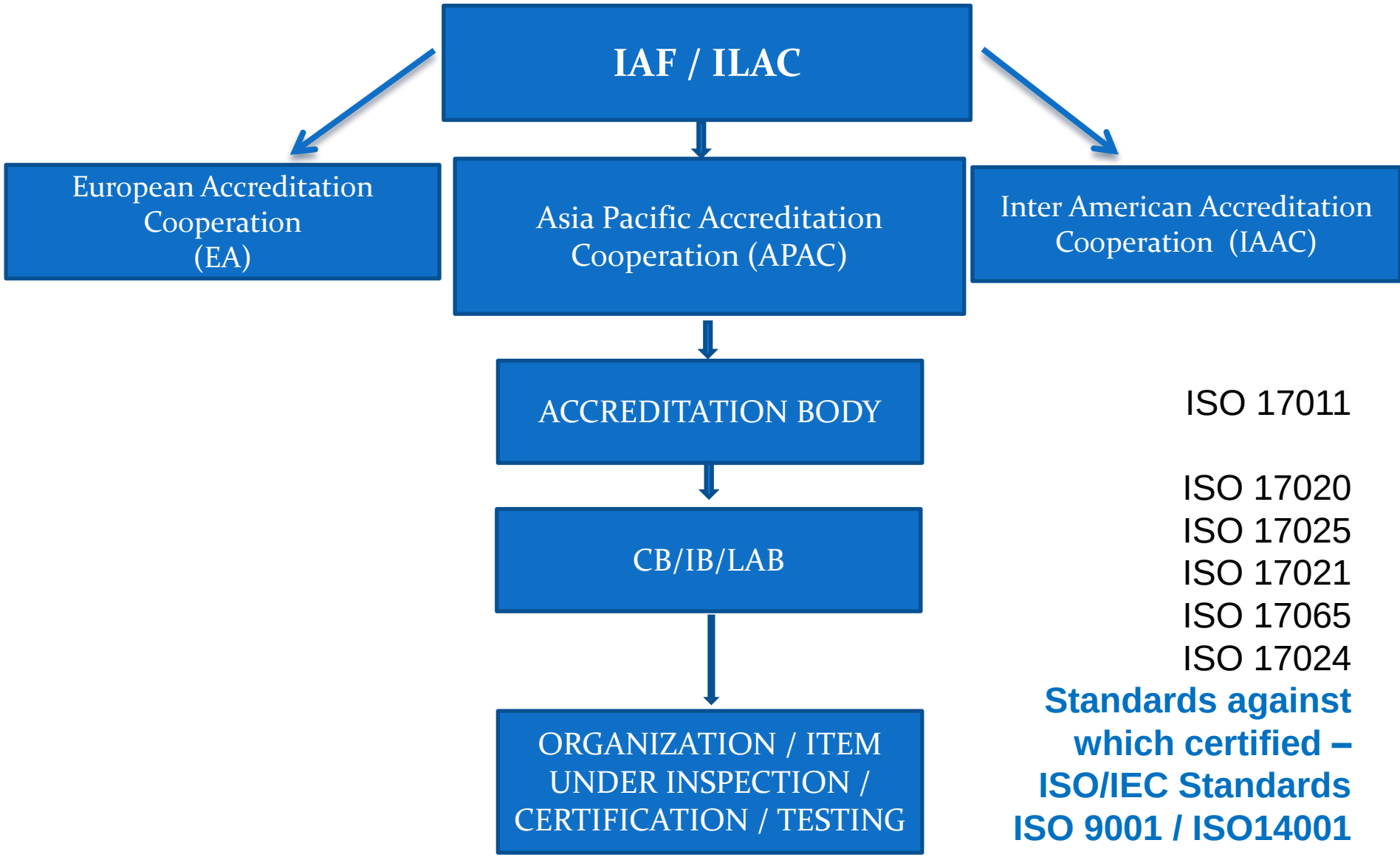
WHY UNAUTHENTIC

- Any one can set up a certification body – no legal bar
- How do you judge it is authentic
- If Govt, you can have trust
- If private, how to trust
- By brand name
- Or word of mouth – your friend recommended it
- Internationally recognized way – it should be **accredited** – then it is under oversight – is impartial, competent, has a process to certify against a recognized standard – and part of an **international system**

INTERNATIONAL SYSTEM

- International Accreditation Forum (IAF) – apex body – global association of accreditation bodies – oversight -MLA
- Regional bodies – broadly each continent – Asia Pacific Accreditation Cooperation (APAC), European Accreditation Cooperation (EA), Inter American Accreditation Cooperation (IAAC), African Accreditation Cooperation (AFRAC), Arab Accreditation Cooperation (ARAC) – oversight over individual ABs – MRA/MLA
- Individual ABs members of regional bodies also – many ABs governmental, many private – national ABs
- Voluntary, non governmental system – increasingly referred to in regulations and free trade agreements
- India - National Acc Board for Certification Bodies/NABCB

EQUIVALENCE FRAMEWORK



ISO 17011

ISO 17020
ISO 17025
ISO 17021
ISO 17065
ISO 17024

Standards against which certified – ISO/IEC Standards ISO 9001 / ISO14001

CONTENTS

- 1. Name and address of the organization certified
- 2. Scope of certification describing its activities under certification – e.g. production, packing and sale of personal protective equipment like coveralls, shoe covers …….(broad list of products)
- 3. Standard (or sometimes scheme or regulation) against which certification is granted e.g. ISO 9001 or ISO 13485 (standard) or ICMED 13485 (scheme) – in general guidance standards are not amenable to certification – these have to be formal, requirement standards or specifications for products or process
- 4. Date of issue and expiry of certificate

CONTENTS *(contd)*

- 5. Unique identification number of the certificate
- 6. Name and address of the CB
- 7. Logo of the CB
- 8. Accreditation symbol indicating the name of the AB which has accredited the CB (in most countries, in the absence of any law requiring certification bodies to register, accreditation is the only way of recognizing a competent, authentic certification body)
- 9. IAF Mark (optional) – indicating that the certificate is covered under the Multilateral Mutual Recognition Arrangement (MLA) of IAF and hence is internationally equivalent and acceptable in the market

QS
QUALITY SERVICE

CERTIFICATE

Certificate no. 8221

ACCUREX

ACCUREX BIOMEDICAL PVT. LTD.

Office: 212, Udyog Mandir No.1, 7/C, Bhagoji Keer Marg,
Mahim (West), Mumbai – 400 016, Maharashtra, India
Factory: G-54, M.I.D.C., Tarapur, Boisar,
Thane – 401 506, Maharashtra, India

QS Zürich AG certifies that the Management System of the above mentioned company has been assessed and meets the requirements established by the following rules:

ISO 13485: 2003 **+ AC:** 2009

The management system includes:

The Development, Manufacture and Supply of Diagnostics Reagents and Test Strips
Trading (Supply) of Diagnostic Reagents and Instruments

EA Sector 23

In the course of the validity of the present certificate the enterprise management system must permanently satisfy the requirements of the international regulations.
The fulfilment of these regulations will be regularly controlled by QS Zürich AG.

For precise and updated information concerning possible changes occurred in the certification object of the present certificate, please contact info@qsindia.com

SWISS

Audit date: 07.05.2012
Date of issue: 11.06.2012
Expiration date: 06.05.2015
Subject to successful annual audit

QS Zürich AG
P.O. Box 6335
CH-8050 Zürich
qs-zuerich@quality-service.ch

SCESm 047
www.sas.ch

Direction

CORRECT NABCB ACCREDITED ISO 9001 CERTIFICATE

qualityaustria central asia

CERTIFICATE

Quality Austria Central Asia Private Limited
(A Division of Peacock Global Company)
Awards this Certificate to

220 KV Substation MPPTCL Sarni

Near ash dam, Sarni, Distt. Betul
(MP)- 460447

Operation and maintenance of 220 KV sub station
for Services in Power Transmission

EAC-25

The validity of this Certificate will be maintained via annual surveillance audits and one renewal audit after three years.

This Certificate confirms the application
and further development of an effective

QUALITY MANAGEMENT SYSTEM
Complying With the requirements of standard
ISO 9001:2008

Registration No.: IND/N/035
Issue Date: 30/07/2016
Expiry Date: 14/09/2018

qualityaustria central asia

NABCB

IAF

India: 30 July 2016
Quality Austria Certification Private Limited (A division of Peacock Global company)

Alok Kumar
Technical Manager

Quality Austria Central Asia Private Limited (A Division of Peacock Global Company) is accredited by National Accreditation Board for Certification Bodies (A Member of IAF MLA) under the Accreditation Number QM 044

For Accreditation and registration details please refer to the applicable regulations and guidelines published on the website of NABCB under "http://www.qcin.org/nabcb/accreditation/nbcb_bod_qms.php" Doc No. PD_24_BODIND

The current validity of the certificate is documented exclusively on the Internet under www.qualityaustriacentralasia.com

CE MARK

- European Regulatory Mark – across product sectors – medical devices, PPEs, electronic goods – various EC regulations/directives
- Many of these products under self declaration of conformity (SDOC) – only higher risk products under 3rd party audits – Notified Bodies – CBs when notified by a regulator
- List of notified bodies on EC website for both MDs and PPEs – separate regulations – maybe in one not in other – to check if certificate from NB – national authorities
- Only in Europe – G-2-G agreement needed – USA/Australia - none in India – branches or associates

WHO SHOULD YOU TRUST

- If the manufacturer/service provider is covered under regulations (e.g. medical devices), it must have regulatory approval for the product category from regulators such as CDSCO
- Organizations having BIS license for use of ISI Mark on their products – voluntary
- Any other certification by a govt agency – e.g. QCI scheme like ICMED certification
- ISO 9001/ISO 13485 certification from an accredited CB under IAF system – preferably accredited by NABCB and carrying NABCB logo
- CDSCO designating NBs – better to go to NBs

WHO SHOULD YOU TRUST *(contd)*

- If the manufacturer claims any other certification like GMP, it should be from a CB accredited by NABCB and carrying NABCB logo or CB under IAF system
- Accreditation means certification against a recognized standard, process is robust and CB has competence
- IAF creating database of certificates for management systems
- If pre-despatch inspection of goods/products or inspection on receipt needed, to use NABCB accredited Inspection Bodies and the inspection report carries NABCB logo – 4 IBs for Textiles Sector right now – competent
- In case of any doubt about certificate, refer to NABCB at nabcb@qcin.org – the best place to go today for ISO certificates

THANK YOU
FOR YOUR ATTENTION!

Any Questions ?