A Cretex Medical company

QTS Medical Device Outsourcing

Are Your Labels EU MDR Ready?

Labeling Impacts of the New European Medical Device Regulation

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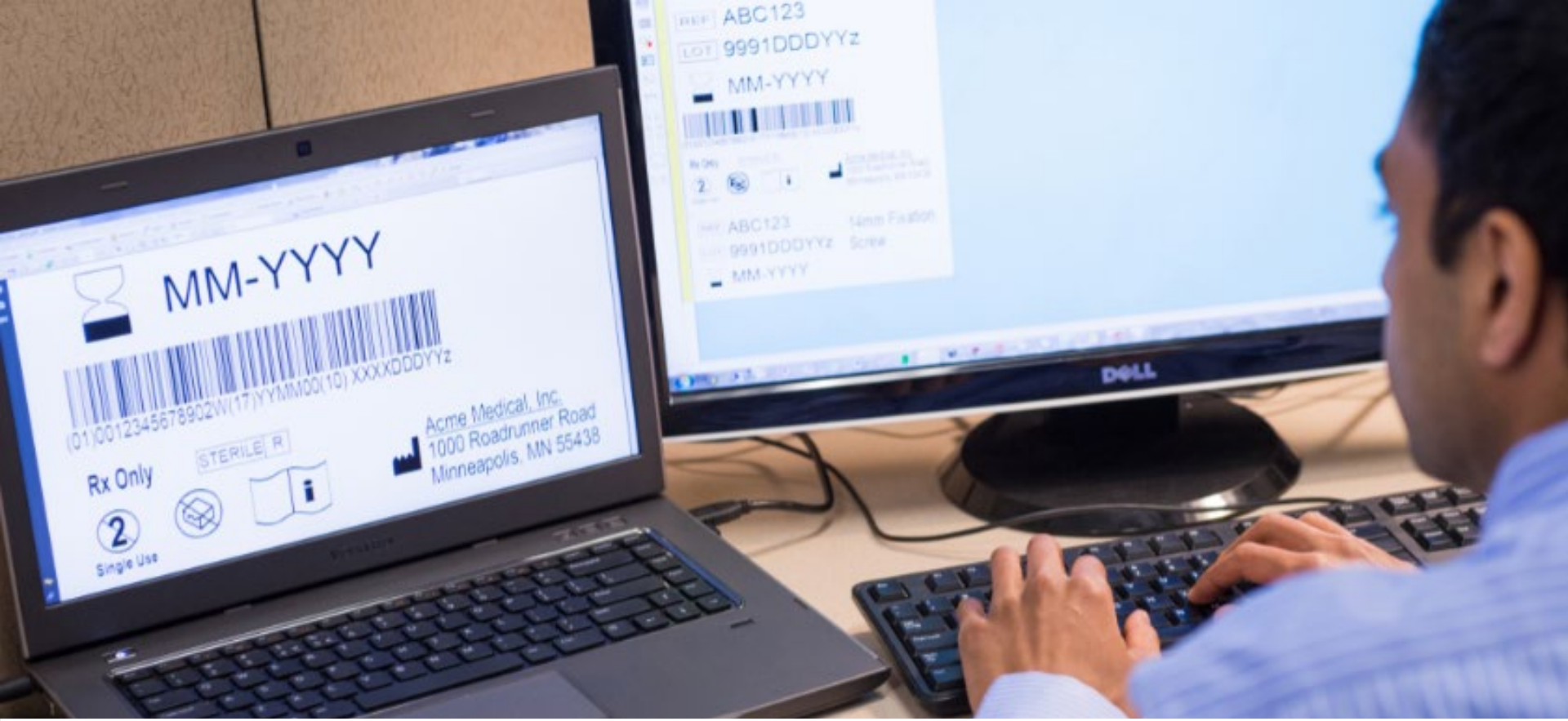
Agenda

- History & Background
- Label Content Changes
- UDI & EUDAMED
- IFUs & Patient Implant Cards
- Key Dates
- How Can QTS Help?

Prominent Disclaimer

What follows is based on the presenter's personal and QTS' collective knowledge regarding EU MDR,UDI and EUDAMED requirements. QTS is not a supplier of regulatory services or advice.

The intent of this presentation is to share our interpretation and best practices with our Customer partners. You are strongly encouraged to research and implement these regulations and guidance in a manner supported by your Quality System(s) and Regulatory resources.



History & Background

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Background

Where We Were: Medical Device Directive (MDD)

- The Council of the European Communities, Council Directive 93/42/EEC
- Official: June 14, 1993
- Several amendments, most recent in 2007

Where We Are Going: Medical Device Regulation (MDR)

- Regulation (EU) 2017|745 of the European Parliament and of the Council of the European Union
- Official: April 5, 2017
- Supersedes the MDD

Renewed Focus on Users

- Technical Knowledge, Experience, Education, Training
- Readily Understood by the Intended User

MDD	MDR
13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users…	23.1(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams…

Renewed Focus on Safety and Transparency

- Device safety and clinical effectiveness **data** is required to be transparently shared with users via EUDAMED and Instructions for Use (IFUs)
- Safety and Effectiveness is Paramount
  - Device certification through equivalency has become more rigorous
  - **Data** is required for **all** submissions

Label Content Changes

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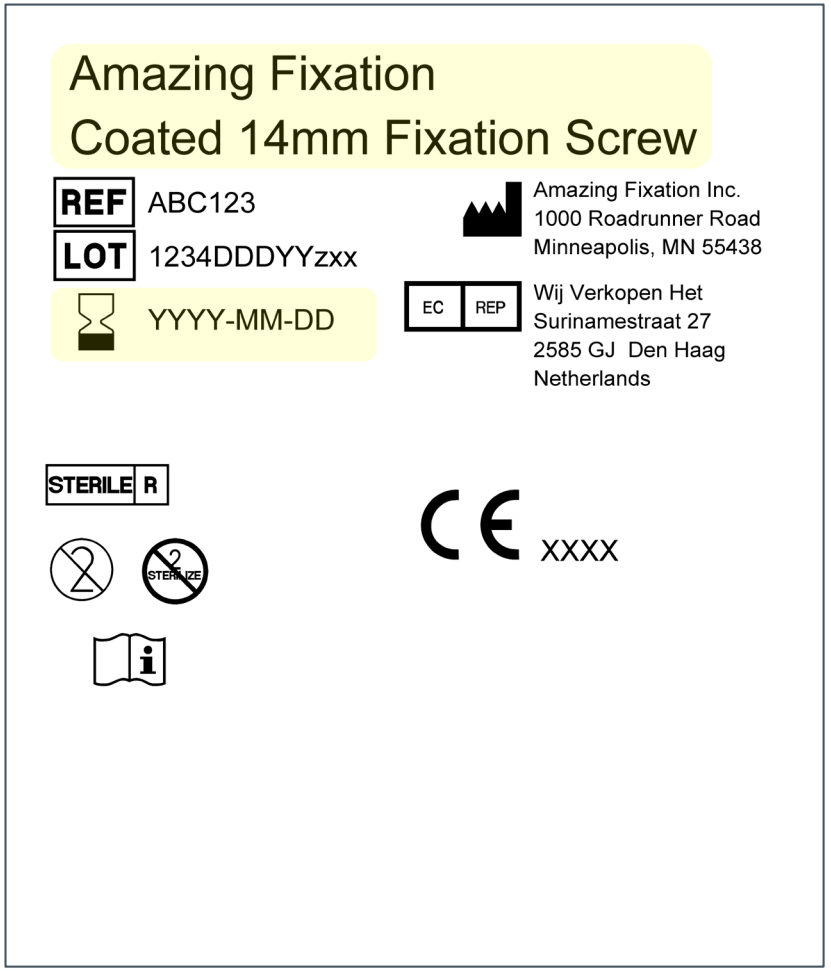
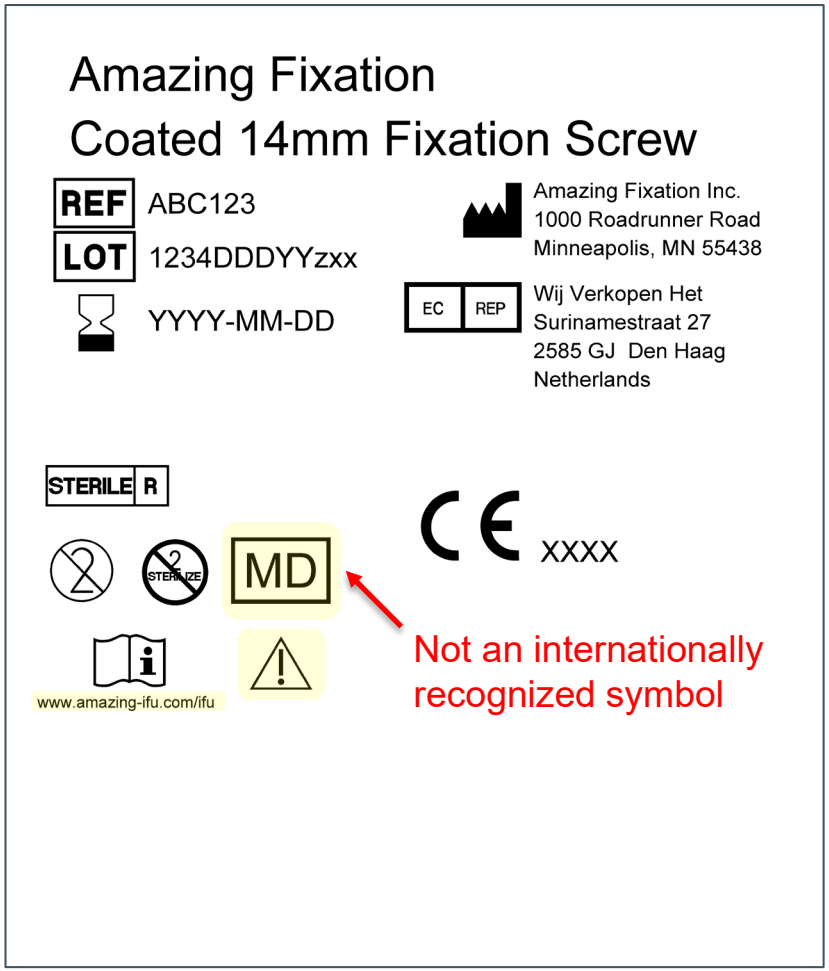
Label Content Changes

- Name or Trade Name of the Device
- Manufacture Date
  (if no Expiration Date)



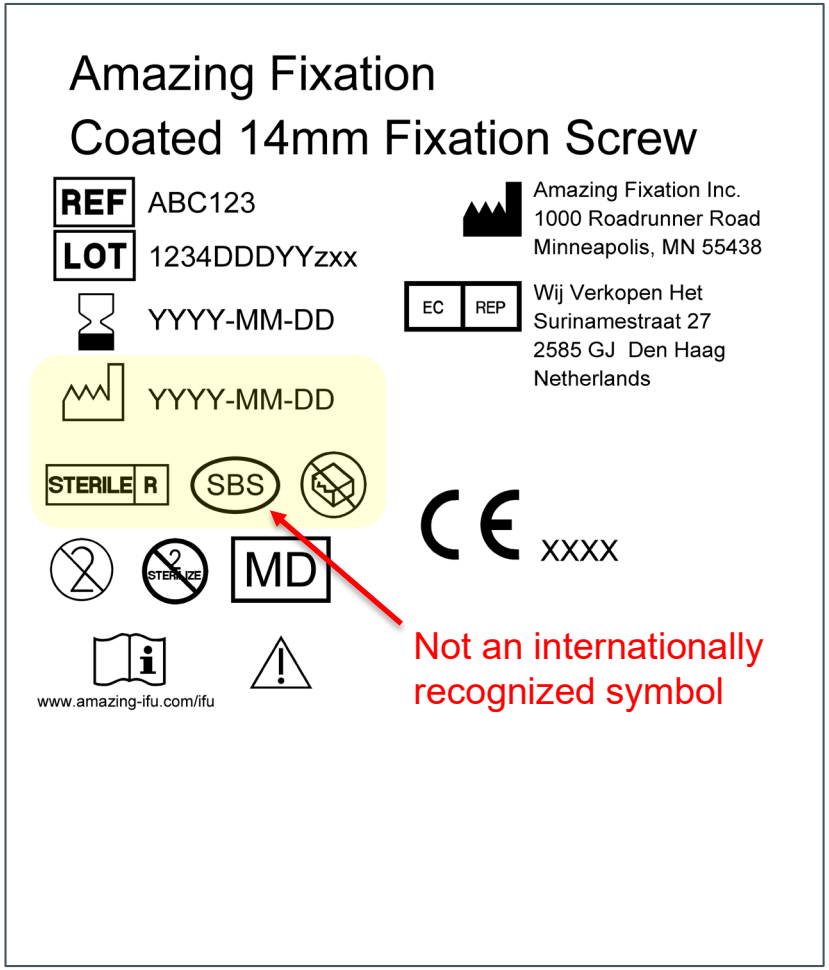
Label Content Changes

- Indication that the device is a **Medical Device**
- Warnings or Precautions that need to be brought to the **immediate attention** of the user
- eIFU
  - Add Web Address



Label Content Changes

- Explicit Requirements for Sterile Barrier Labeling
  - Identification the sterile barrier
  - Declaration of the Sterile Condition (e.g. Sterile, Non-Sterile)
  - Sterilization Method
  - Manufacture Date (Month & Year)
  - Expiration Date (Month & Year)
  - Directive to check IFU if package appears damaged



Label Content Changes

- Absorbed Materials
  - Overall composition for absorbed devices and quantitative information on the main constituent(s)

Label Content Changes

Items Not Applicable to our Label

- Number of times a single-use device has been reprocessed
- Serial Number is required for all active implantables

Label Content Changes

Items Not Applicable to our Label

- Specific warning for devices including substances that are:
  - Carcinogenic
  - Mutagenic
  - Toxic to reproduction
  - Endocrine-disrupting properties
- Indication that the device contains tissue or cells of animal or human origin

Label Comparison

Amazing Fixation
Coated 14mm Fixation Screw

REF ABC123
LOT 1234DDDYYzxx
YYYY-MM-DD

Amazing Fixation Inc.
1000 Roadrunner Road
Minneapolis, MN 55438

EC REP
Wij Verkopen Het
Surinamestraat 27
2585 GJ Den Haag
Netherlands

STERILE R

CE XXXX

Amazing Fixation
Coated 14mm Fixation Screw

REF ABC123
LOT 1234DDDYYzxx
YYYY-MM-DD
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Amazing Fixation Inc.
1000 Roadrunner Road
Minneapolis, MN 55438

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2585 GJ Den Haag
Netherlands

STERILE R SBS

MD

CE XXXX

www.amazing-ifu.com/ifu

1.0 mg MATERIAL

Unique Device Identification

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UDI = Unique Device Identification

- Very similar to the US FDA rule
- Unique identifying “part numbers” issued by a neutral party; assigned to your finished products
- Product packaging must be labeled with the UDI
- Some products must bear the UDI on the product itself (Direct Part Marking)
- UDIs must be registered in a database (EUDAMED)

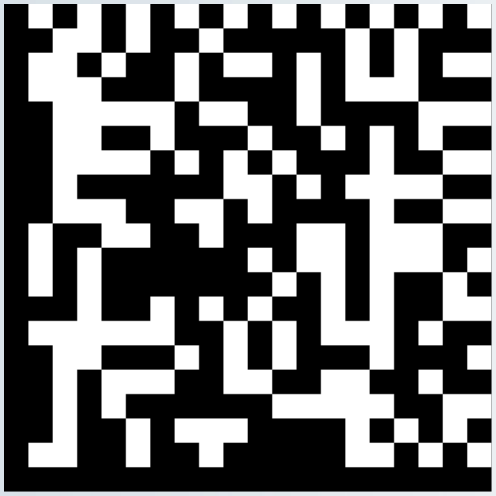
Why UDI?

- Required to place a unique identifier
  - Non-partial agency
  - On packages and sometimes products
- Required to place certain production information
  - Machine-readable form
- Why do we do this?
  - Serves as the “primary key” of the regulatory database
  - Part numbering scheme may be the same as another

Designated Issuing Agencies

Composition of a UDI Symbol

Device Identifiers + Production Identifiers = UDI



(01)10123456789125 → Device Identifiers

(17)000101

(10)0000DDDYYzxx → Production Identifiers

Composition of a UDI Symbol

Device Identifier:

- Version or model of the device
- Labeler of the device
- Package quantity (unit of sale, multi-pack, etc.)
- Issued by your agency

(01)10123456789125 → Device Identifiers

(17)000101

(10)0000DDDYYzxx → Production Identifiers

Composition of a UDI Symbol

Production Identifier:

- Conditional, Variable
- Identifies the following IF included on the Device Label
  - Lot/Batch Number
  - Serial Number
  - Software Identification
  - Expiration Date
  - Manufacturing Date (if no expiration date)

(01)10123456789125 → Device Identifiers

(17)000101

(10)0000DDDYYzxx → Production Identifiers

Location of UDI Symbol

- Label of the Device and all Higher Levels of Packaging
  - Primary package of the device
  - Multi-pack sales units
  - ✓*Does NOT include shipping containers*
- Reusable Devices
  - Device itself must be marked
  - Remain throughout the intended lifetime of device
  - ✓*Some exclusions*

EUDAMED

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What is EUDAMED?

- European Databank on Medical Devices
- Currently exists, and use has been mandatory for use since 2011
- MAJOR overhaul for MDR
- Planned Launch Date of March 25, 2020

MDR / EUDAMED / UDI Structure

EUDAMED
European MD/IVD Database

CERTIFICATES
- Issued
- Suspended
- Withdrawn
- Refused
- Restricted

VIGILANCE
- Serious Incidents
- FSCA
- FSN
- Corrective Actions

CLINICAL INVESTIGATION
- Sponsor
- Purpose
- Status
- Approval
- Summary

MARKET SURVEILLANCE
- Measures taken by MS
- Preventative health measures
- Non-compliant devices

UDI Registration for Devices
Registration of Manufacturers and Economic Operators

Instructions For Use

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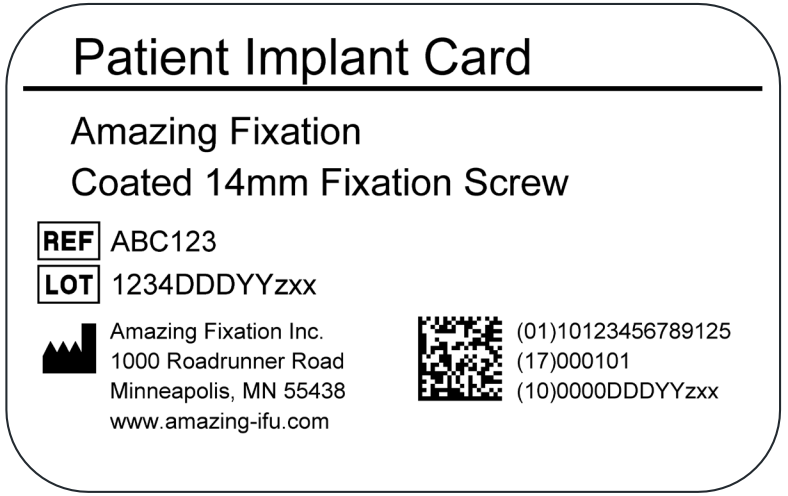
IFU Changes

- Many Changes:
  - MDD has 17 sub-sections, MDR has 28 sub-sections
  - MDR sub-sections are much more descriptive
- Highlights:
  - Specification of the expected clinical benefits
  - Links to data on clinical performance and safety (EUDAMED)
  - Special training and/or facilities required to use the device
  - Information on the correct installation, operation and maintenance of the device
  - What to do if the sterile barrier appears damaged
  - Information on the reuse of single-use devices
  - Expanded requirements for warnings to the users

Patient Implant Cards

- New Requirement; Only Applies to Implants
- Required Info
  - Device Name
  - Serial Number and/or Lot Number
  - UDI
  - Device Model
  - Manufacturer Name, Address & Website



- Health Institutions Required to Provide Rapid Access to Additional Information


14mm Fixation Screw
REF
ABC123
LOT
1234DDDYYzxx
STERILE R
YYYY-MM-DD
(01) 12345678901231
(17) 000101
(10) 1234DDDYYzxx
Acme Medical Inc
1000 Roadrunner Road
Minneapolis, MN 55430

Next Steps

Key Dates

WHEN	WHAT	NOTES
November 2017	Notified Body designation process begins	EU pares down the list of approved organizations for accepting and certifying products
May 26, 2020	All device certifications and recertifications must be performed under MDR	
May 26, 2022	All certifications and recertifications must be performed under IVDR	
May 26, 2024	All MDD and IVDD certificates become void.	Any medical devices or IVDs to be sold must have MDR/IVDR certificates.
May 26, 2025	All medical devices and IVDs put into service, must have MDR/IVDR certificates.	Nothing certified under the old system can be used for the first time.

How can QTS help you succeed?

Expertise

- GS1 and HIBCC barcodes
- Label symbology updates

Industry Partners

- IFUs and printed content

Cretex Medical Partners

- Direct Part Marking

Q&A Session

Connect with QTS:

- Contact your QTS Account Manager
- Email: info@qtspackage.com
- Online: qtspackage.com
- Phone: 952.942.8321
- Social Media:

Resources & References

- Regulation (EU) 2017|745 of the European Parliament and of the Council of the European Union (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745)
- GS1 Website (www.GS1.org)
- GS1 Guide on Unique Device Identification (UDI) implementation in the USA and in the EU (https://www.gs1.org/sites/default/files/docs/healthcare/position-papers/gs1_udi_guide_final_20170324.pdf)
- Health Industry Business Community Council (HIBCC) Website (www.HIBCC.org)
- International Council for the Commonality in Blood Banking Automation (ICCBBA) Website (www.iccbba.org)
- *ISO/IEC 15415:2011 – Information Technology – Automatic identification and data capture techniques - Bar code symbol print quality test specification – Two-dimensional symbols*
- *ISO/IEC 15416:2000 – Information Technology – Automatic identification and data capture techniques - Bar code print quality test specification – Linear symbols*
- QTS Resources Page (https://qtspackage.com/medical-device-resources/)

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Thank You.

Quality Tech Services, LLC

www.qtspackage.com

952-942-8321

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