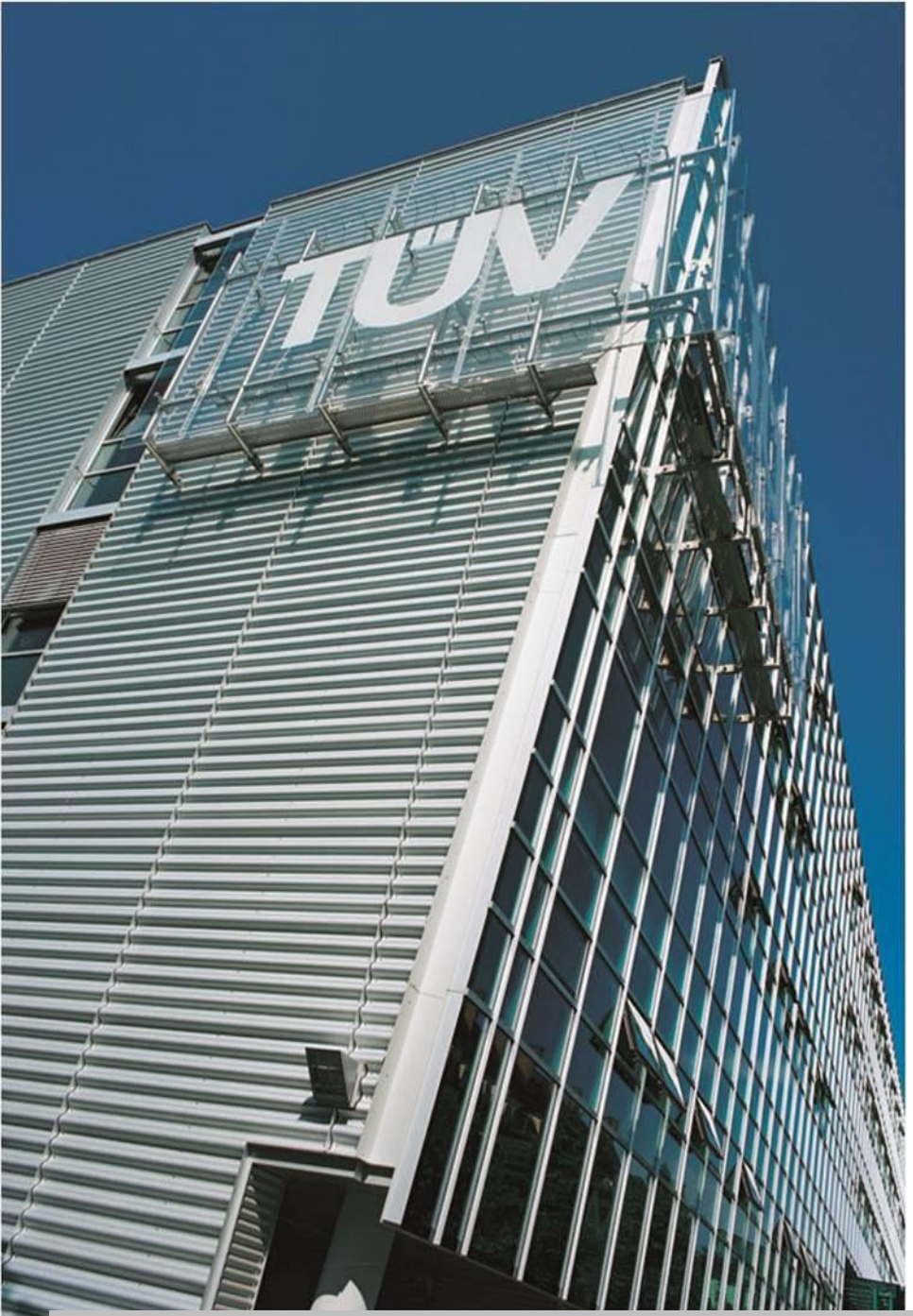

Product Service

Choose certainty.
Add value.

Control over supply and distribution chains

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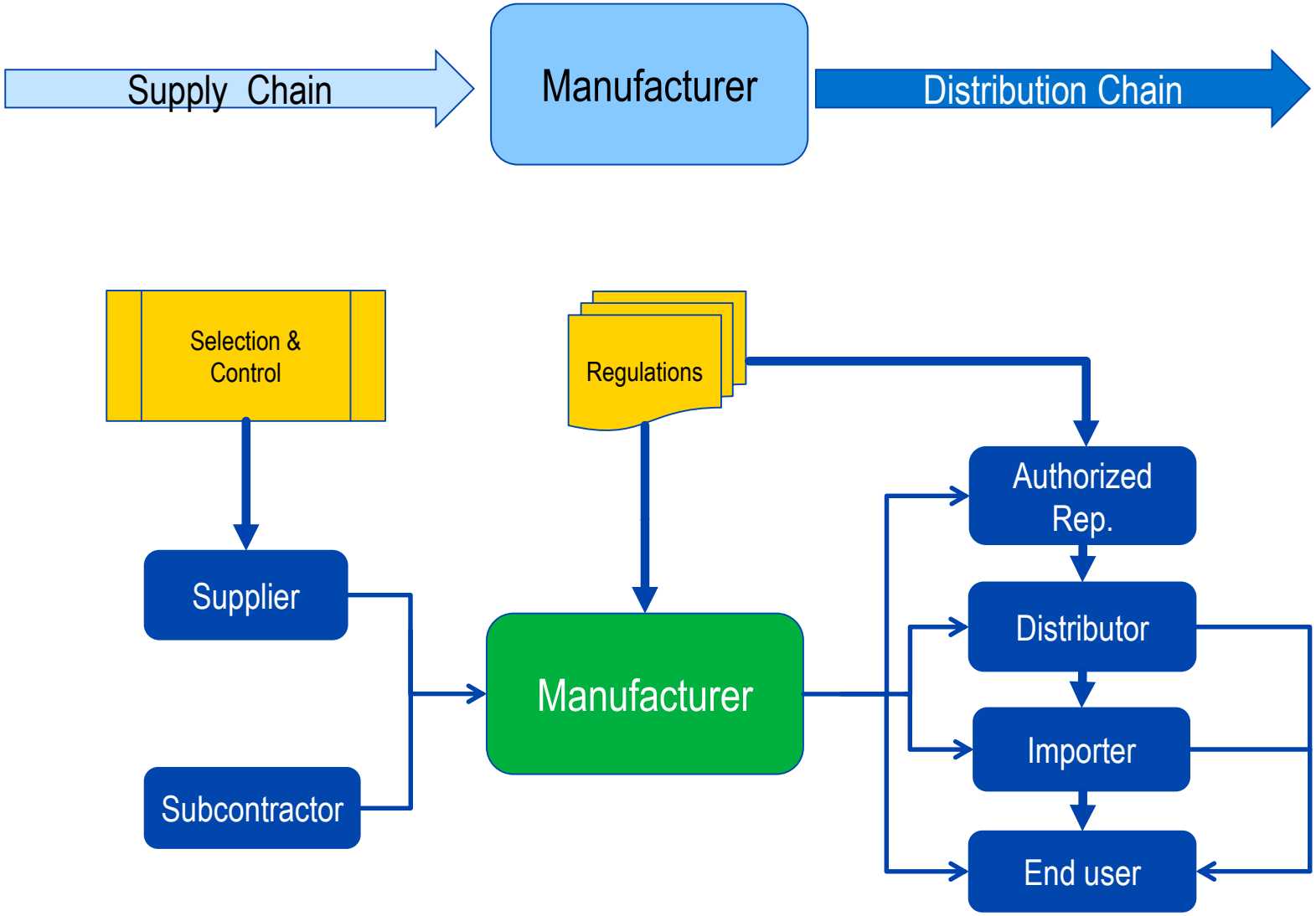

Supply Chain
Manufacturer
Distribution Chain
Selection & Control
Regulations
Supplier
Subcontractor
Manufacturer
Authorized Rep.
Distributor
Importer
End user

Quality Management System for all

Article 10:

The quality management system shall address at least the following aspects:

(d) resource management, including selection and control of suppliers and sub-contractors;

Annex IX (2.3)

The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

3.4. The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors,

Annex IX

2.3 The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes

3.4. The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors

Manfucturer:

- Selects supplier/subcontractor
- Controls supplier/subcontractor

Notified Body:

- Audit selection process / criteria
- Audit control process / criteria
- Audit supplier/subcontractor, if applicable

Distribution Chain

Traceability, traceability, traceability……

European UDI System for both traceability and regulatory purpose

Description of the European UDI System is described in Article 27

…. The Unique Device Identification system ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, …

Identification within the supply chain

1. Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.
2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8):
    (a) any economic operator to whom they have directly supplied a device;
    (b) any economic operator who has directly supplied them with a device;
    (c) any health institution or healthcare professional to which they have directly supplied a device.

Article 27

Subclause 8:

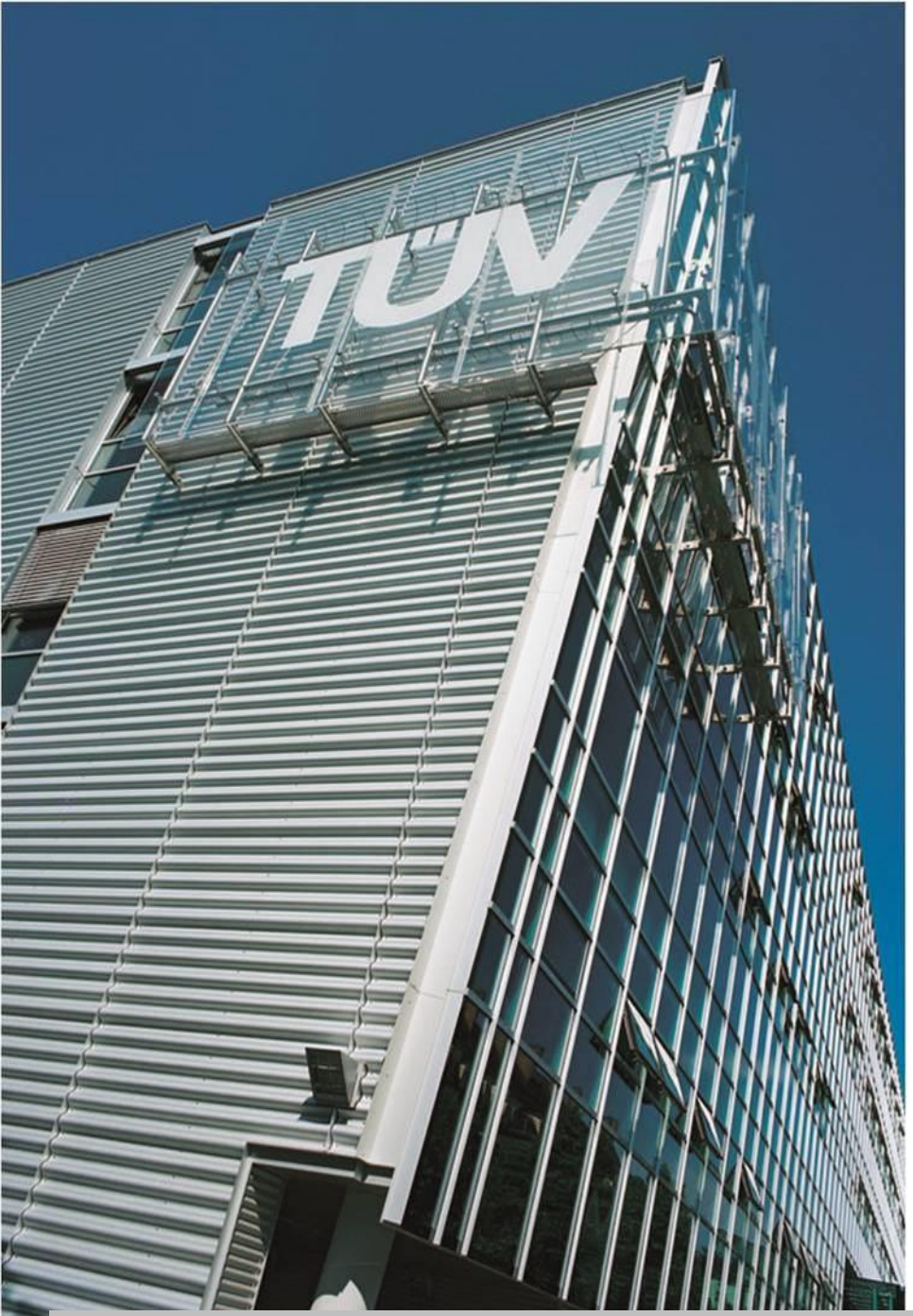
Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to:

— class III implantable devices;

— the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11 (delegated act)

What does that mean for implantable Class III ?

- Requirements on the distribution of implantable class III devices, active and non-active



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