VIDEOTON

VT ElektroPlast

ONE COMPANY – INFINITE POSSIBILITIES

Quality Management

www.vtep.videoton.hu

CONTENT

- Certified standards
- Quality staff
- Documentation system
- Process Map
- Quality management system development
- Supplier evaluation, development, sourcing
- Trainings
- Measurement equipment calibration
- Specific requirements
- Applied quality technics
- Test lab
- Measurement lab

VIDEOTON

CERTIFIED STANDARDS – VTEP/VTBT

ISO 9001:2015

Scope:

- Component assembly and injection moulding parts manufacturing

CERTIFIED STANDARDS – VTEP/VTBT

IATF 16949:2016

Scope:

- component assembly and injection moulding parts manufacturing

VIDEOTON

CERTIFIED STANDARDS - VTEP

ISO 13485:2016

Scope:

- Manufacture of injection moulded plastic parts and assembly of products for medical device manufacturers and assembly of in vitro diagnostic medical devices (hemostasis instrument) according contract manufacturing

Certificate of Registration

This certificate has been awarded to

Videoton Elektro-PLAST Kft.

H-7400 Kaposvár, Izzó u. 3., Hungary

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below:

Manufacture of injection moulded plastic parts and assembly of products for medical device manufacturers and assembly of in vitro diagnostic medical devices (hemostasis instruments) according contract manufacturing

Tanúsítvány

Videoton Elektro-PLAST Kft.

H-7400 Kaposvár, Izzó u. 3., Hungary

ISO 13485:2016

Fröccsöntött műanyag alkatrészek gyártása és termékek összeszerelése az orvostechnikai eszközgyártók számára valamint in vitro diagnosztikai orvostechnikai eszközök (hemosztázis készülékek) szerződés szerinti összeszerelése

VIDEOTON

QUALITY STAFF

Workshop QA manager	4
Quality engineer	15
SQA engineer	2
Supplier development engineer	1
Supplier quality technician	2
Quality technician	9
Incoming inspector	4
Quality inspector	26
Total:	**63**

VIDEOTON

DOCUMENTATION SYSTEM

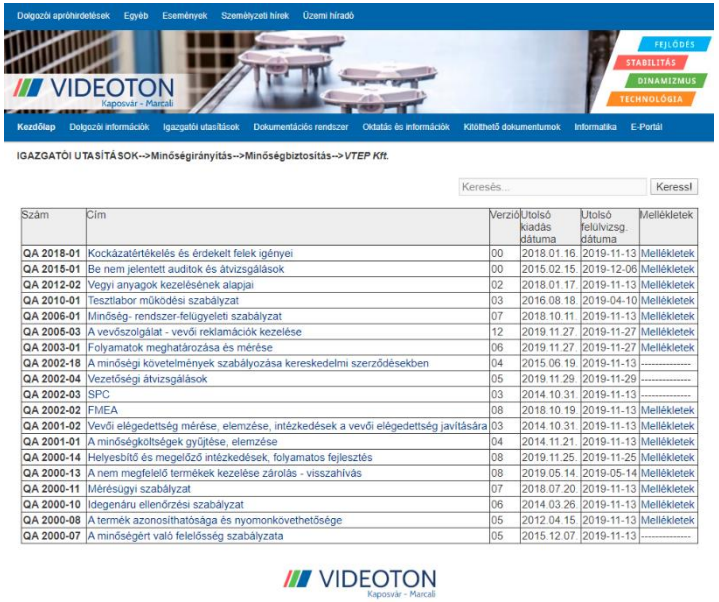
Electronic system on a safe intranet with authorized access

Level 1 Quality Manual

Level 2 Standard Operation Procedures

Level 3 Work Instructions

Level 4 Records



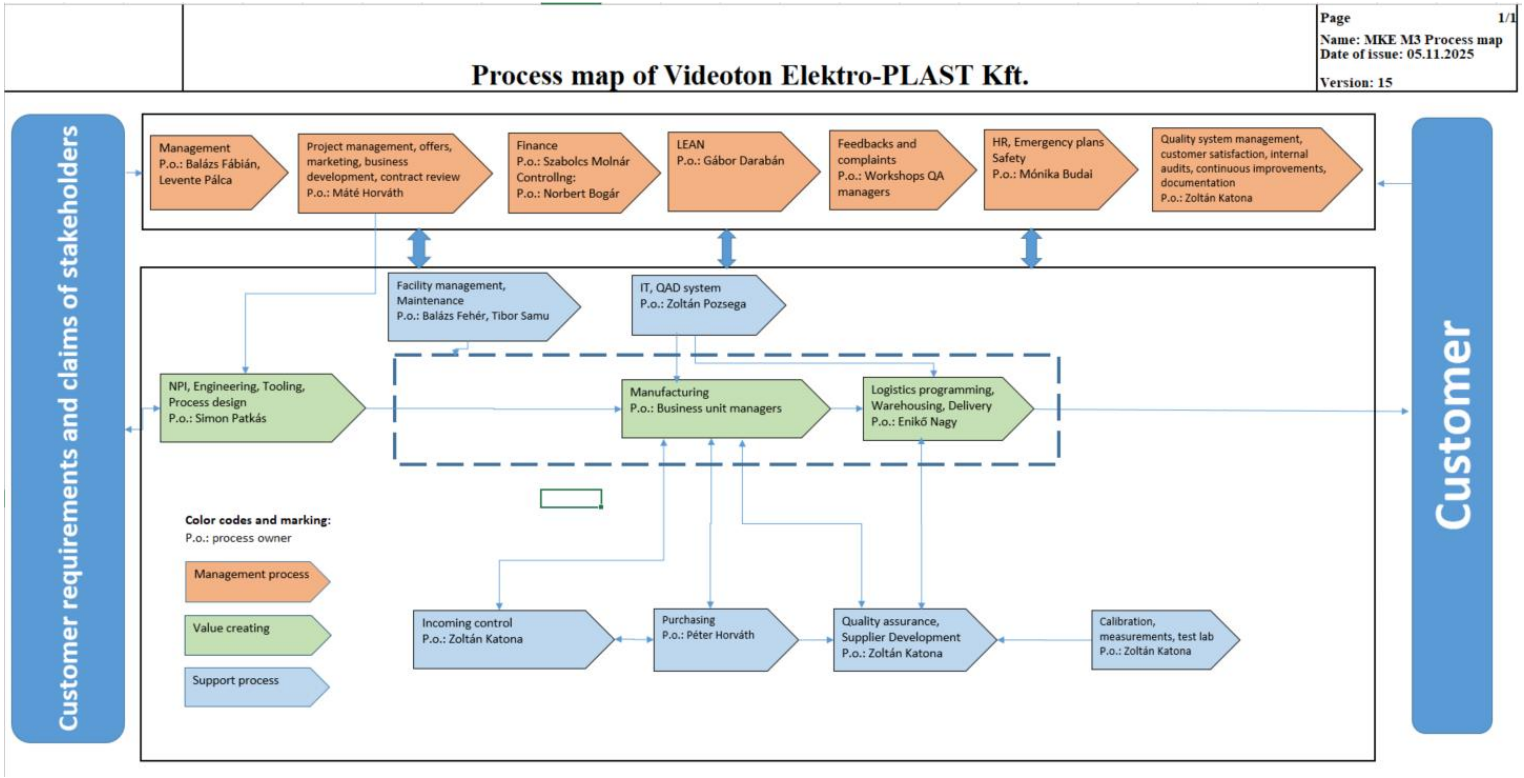
Szám	Cím	Verzió	Utolsó kiadás dátuma	Utolsó felülvizsg. dátuma	Mellékletek
QA 2018-01	Kockázatértékelés és érdekelt felek igényei	00	2018.01.16.	2019-11-13	Mellékletek
QA 2015-01	Be nem jelentett auditok és átvizsgálások	00	2015.02.15.	2019-12-06	Mellékletek
QA 2012-02	Vegyi anyagok kezelésének alapjai	02	2018.01.17.	2019-11-13	Mellékletek
QA 2010-01	Tesztlabor működési szabályzat	03	2016.08.18.	2019-04-10	Mellékletek
QA 2006-01	Minőség- rendszer-felügyeleti szabályzat	07	2018.10.11.	2019-11-13	Mellékletek
QA 2005-03	A vevőszolgálat - vevői reklamációk kezelése	12	2019.11.27.	2019-11-27	Mellékletek
QA 2003-01	Folyamatok meghatározása és mérése	06	2019.11.27.	2019-11-27	Mellékletek
QA 2002-18	A minőségi követelmények szabályozása kereskedelmi szerződésekben	04	2015.06.19.	2019-11-13	----------
QA 2002-04	Vezetőségi átvizsgálások	05	2019.11.29.	2019-11-29	----------
QA 2002-03	SPC	03	2014.10.31.	2019-11-13	----------
QA 2002-02	FMEA	08	2018.10.19.	2019-11-13	Mellékletek
QA 2001-02	Vevői elégedettség mérése, elemzése, intézkedések a vevői elégedettség javítására	03	2014.10.31.	2019-11-13	Mellékletek
QA 2001-01	A minőségköltségek gyűjtése, elemzése	04	2014.11.21.	2019-11-13	Mellékletek
QA 2000-14	Helyesbítő és megelőző intézkedések, folyamatos fejlesztés	08	2019.11.25.	2019-11-25	Mellékletek
QA 2000-13	A nem megfelelő termékek kezelése zárolás - visszahívás	08	2019.05.14.	2019-05-14	Mellékletek
QA 2000-11	Mérésügyi szabályzat	07	2018.07.20.	2019-11-13	Mellékletek
QA 2000-10	Idegenáru ellenőrzési szabályzat	06	2014.03.26.	2019-11-13	Mellékletek
QA 2000-08	A termék azonosíthatósága és nyomonkövethetősége	05	2012.04.15.	2019-11-13	Mellékletek
QA 2000-07	A minőségért való felelősség szabályzata	05	2015.12.07.	2019-11-13	----------

VIDEOTON
Kaposvár - Marcali

- Processed based documentation
- PPAP documents for all products and produced parts
- All the documentations are available for authorized users

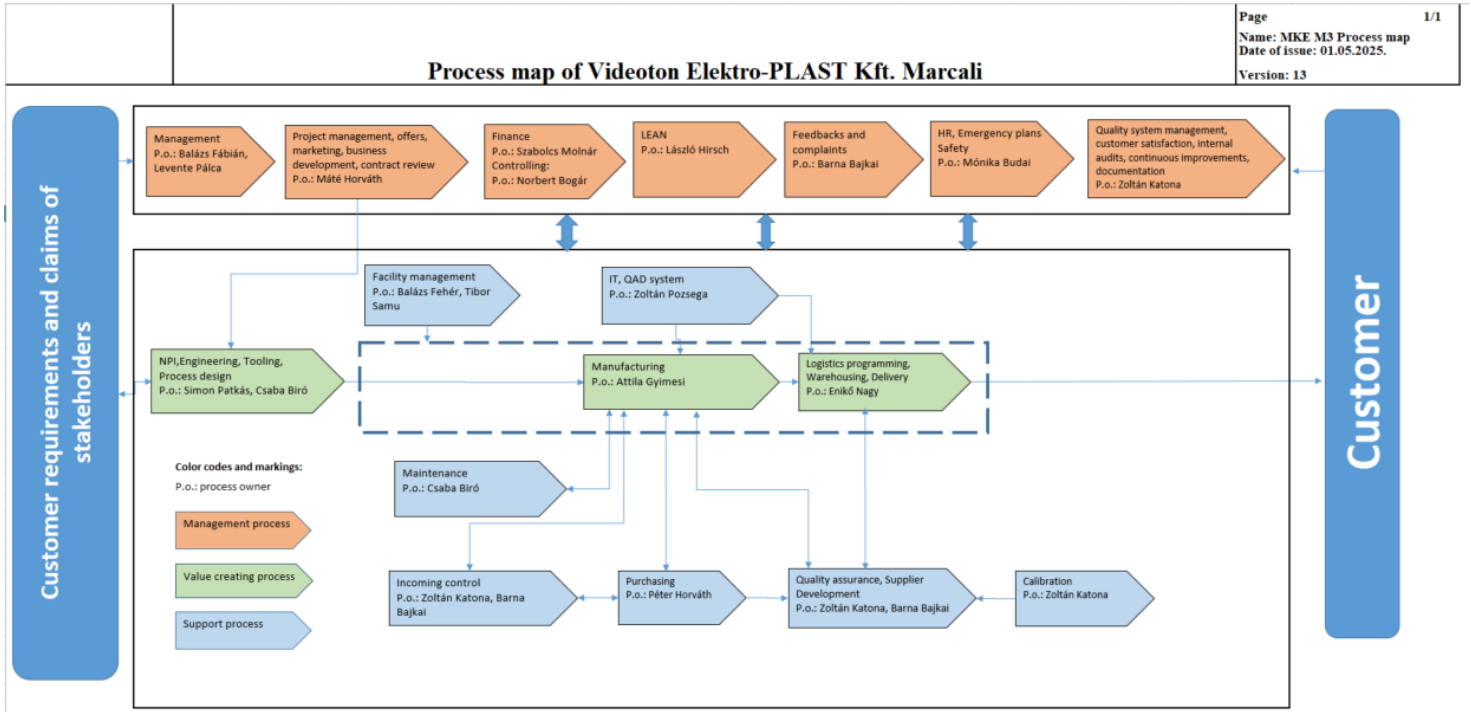
VIDEOTON

PROCESS MAP - VTEP



VIDEOTON

PROCESS MAP - VTBT



VIDEOTON

QUALITY MANAGEMENT SYSTEM DEVELOPMENT

Regular internal audits (system and process) based on a yearly plan

It ensures the quality system is consistently in a state of control

Management review

Ensures that the Quality Management System achieves the established objectives with a successful and effective operation

CAPA (Corrective Action/ Preventive Action)

Ensures that quality system issues are identified, analysed and corrected in a proactive manner to keep quality system effective

Quality Improvement Plan

Determines improvement actions for all the departments on a yearly base

VIDEOTON

SUPPLIER EVALUATION, DEVELOPMENT, SOURCING

Monthly based evaluation on

- Quality performance
- Delivery performance

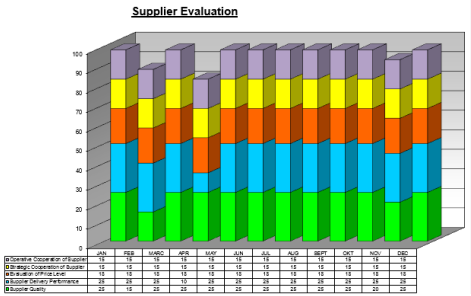
Suppliers are ranked

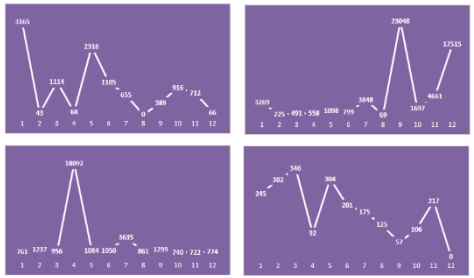
A - B - C - D categories

Monthly detailed evaluation

Focus on C and D category suppliers (improvement requests)

PPM Performance monitoring





VIDEOTON

SUPPLIER EVALUATION, DEVELOPMENT, SOURCING

Supplier development

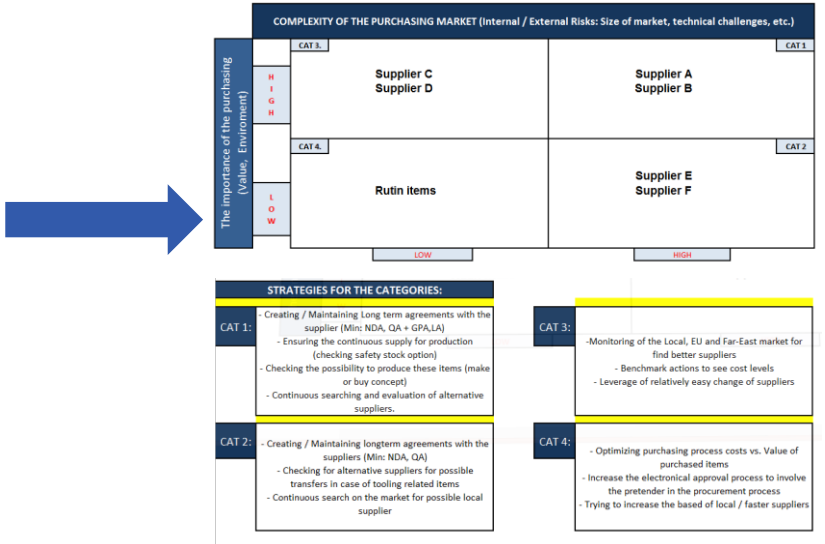
- Dedicated Supplier Development Engineer
- Support in quality issues for SQA engineers in supplier related quality problems
- Visits and audits at suppliers
- Improvement of communication and co-operation
- Monitoring of Reach, RoHS, Conflict Mineral, IMDS, Food Contact, BOMcheck with declarations
- Suggestions and requirements for improvements
- Determine short– and long-term improvement actions
- Pre-qualification in the case of new suppliers

VIDEOTON

SUPPLIER EVALUATION, DEVELOPMENT, SOURCING

Strategic purchasing

- Commodity driven Sourcing Team
- Supplier classification based on Kraljic matrix
- Continuously updated supplier database
- Seeking and pre-qualifying of new suppliers
- Agreements with suppliers
- Optimization of commercial conditions
- Defining strategic actions toward suppliers, based on classification (Development / Hold / Phase Out / make or buy)
- Defining Road map for development of suppliers



VIDEOTON

TRAININGS

Wide-spread trainings for all workers at entrance

(plus half-yearly and yearly) with examination

- Quality (based on ISO 9001, IATF 16949 and ISO 13485 standards)
- Labour-safety (based on ISO 45001)
- Environment (based on ISO 14001)
- Energy management (based on EN ISO 50001–VTEP)
- Dress rules
- General (rules, ethics, culture)

TRAININGS

Extended trainings for white-collar workers:

- according to the professional field
- further trainings for improving skills (competence, language)
- specialized trainings for management

Regular (monthly) training for blue-collar workers based on:

- operation instruction, failure cards, customer feedbacks etc.
- yearly training plan to improve worker skills

VIDEOTON

MEASUREMENT EQUIPMENT CALIBRATION

Internal calibration - Mostly simpler equipment: calipers, micro meters, scales, feeler gauges, dials, simple electronic measurement equipment etc.

External calibration - All the special measurement equipment, which require external laboratory: coordinate measurement machine, torque meters, functional testers, complex electronic measurement equipment etc.

- More than 1500 pcs measurement equipment
- Electronic data base for proper tracing of validation deadlines
- Calibration in temperature controlled measurement lab

SPECIAL REQUIREMENTS

FDA (Food and Drug Administration)

At VTEP, it ensures the manufacturing of safe medical devices complying with the mandatory regulation of 21 CFR Part 820 (Quality System Regulation) for the US market. FDA currently applied at Philips medical products.

I-Quality

Requirements for companies, who manufactures Products for P&G (Braun). Determines major principles for Quality Management System. Currently applied at Braun Shaver Cleaning Center products.

VIDEOTON

SPECIAL REQUIREMENTS

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)
Its major element is to communicate information on chemicals through the supply chain to restrict the usage of them. It covers those chemicals, that can have potential negative impacts on human, health or environment

RoHS (Restriction of Hazardous Substances Directive)
This directive restricts the use of six hazardous Materials of various types of electronic and electrical equipment:
Lead (Pb), Mercury (Hg), Cadmium (Cd),
Hexavalent chromium (Cr6+), Polybrominated, biphenyls (PBB),
Polybrominated diphenyl ether (PBDE)

VIDEOTON

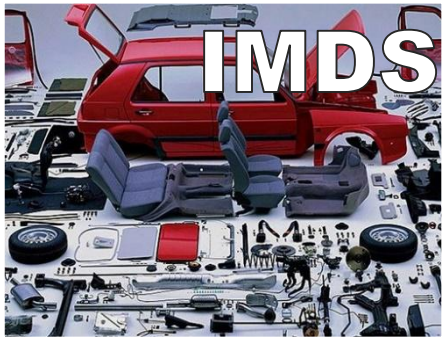
SPECIAL REQUIREMENTS

Food contact materials

Materials that are intended to be in contact with food. It determines strict rules for manufacturing, packaging and warehousing of parts and products contacting with food.

IMDS (International Material Data System)

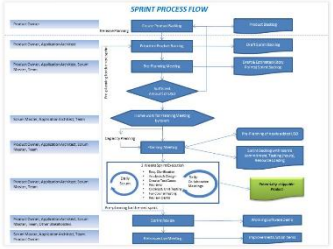
In the automotive products, it is a requirement to collect information about the used materials (and hazardous content), which must be declared in material data sheet into the IMDS. All supplier must submit data about the parts that sells to customer.



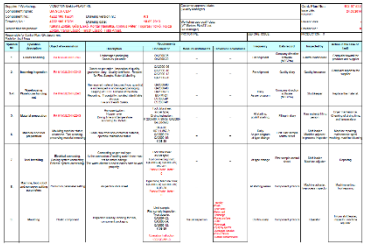
VIDEOTON

APPLIED QUALITY TECHNICS

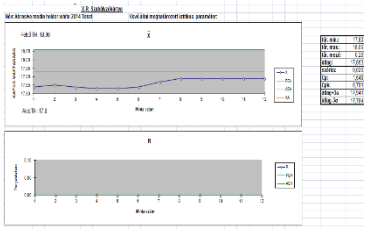
Process flow chart



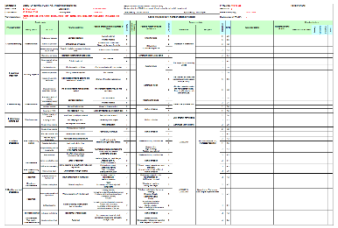
Control Plan



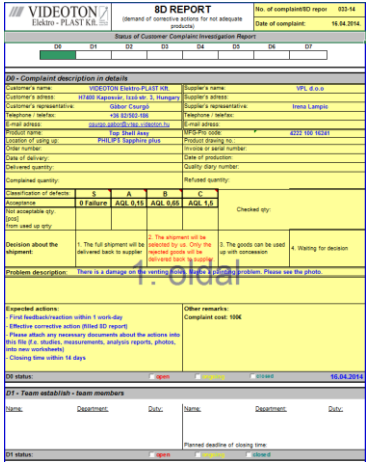
SPC



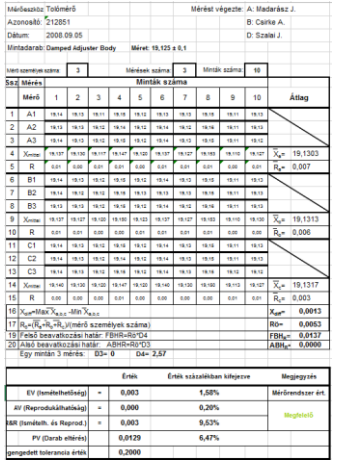
PFMEA - DFMEA



8D report



MSA Gauge R&R



TEST LAB

Test types

- Product design tests
- Product release test
- Battery tests in separated test lab
- Product functionality - related test
- Product performance - related test
- RoHS compliance
- Approbation pre-tests
- Climatic tests in temperature and humidity chambers
- Internal test for investigation of quality problems

Measurement equipment

- Programmable AC Power Source (Chroma 6530, Chroma 63113A)
- Insulation/Current Leakage tester (GW Instek GPI-745A)
- Power analyzer (Yokogawa WT210 + GPIB)
- Digital multimeter (Picotest M3500A, Keysight 34461A)
- Hi-pot tester (Hioki 3561-01)
- Force/torque meter (Mecmesin AFG 500)
- Static torque wrench (Mecmesin TW15)
- Contactless RPM meter

XRF TESTER
(RoHS)

TEMPERATURE
AND HUMIDITY
CHAMBER

VIDEOTON

MEASUREMENT LAB

Major activity

Measurement in connection with:

- Initial sample approvals
- Quality problem investigation
- Tool approval, optimization or reparation
- Special demand from customer
- R&D

Measurement equipment

- Keyence IM-7020 image measurement system
- Atos 3D scanner
- Dea Global CMM
- Global performance cmm
- Optiv classic optical cmm
- Tesa visio optical cmm
- Tesa cmm
- Tinius Olsen tensile testing equipment
- Torque meter
- Scale
- Surface roughness meas.
- Hardness meas.

OPTICAL CMM

CMM

3D SCANNER

VIDEOTON

VIDEOTON

THANK YOU FOR YOUR KIND ATTENTION!

VIDEOTON
VT ElektroPlast

VIDEOTON Elektro-PLAST Kft.
H-7400 Kaposvár
3 Izzó Str.
Phone: + 36 82 502 100
vtep@vtep.videoton.hu

Zoltán Katona
Quality Manager
Phone: + 36 82 502 328
Mobile: + 36 20 247 8730
katona.zoltan@vtep.videoton.hu

AAA®
Highest creditworthiness

www.vtep.videoton.hu