CONFORMITEITSVERKLARING
Declaration of Conformity

Medex Instrumenten Service verklaart een ISO 13485 gecertificeerd kwaliteitsmanagementsysteem met inbegrip van processen conform richtlijn medische hulpmiddelen 93/42/EEC, annex VII.3 en VII.4 te hebben geïntroduceerd en te hanteren bij productie van medische hulpmiddelen uit de volgende productgroepen:

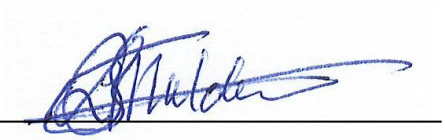
Medex Instrumenten Service declares that it has introduced and applies a ISO 13845 certified quality management system including processes conforming to annex VII.3 and VII.4 of Medical Devices Directive 93/42/EEC for producing the medical devices of the following product groups:

Productgroep:	*Zie bijlage*
Product group:	*See appendix*
Klassificatie:	Klasse I – regel 6 Conform Bijlage IX van de Richtlijn 93/42/EEG
Classification:	*Class I – rule 6* *Conform Annex IX to the Council Directive 93/42/EEC*

Deze hulpmiddelen voldoen aan de essentiële eisen van de richtlijn medische hulpmiddelen 93/42/EEG, bijlage I, ISO 13485:2016, ISO 14971:2019 en EN ISO 15223-1:2016.

These devices are conform with the Essential Requirements of the Medical Device Directive 93/42/EEC, annex I, ISO 13485:2016, ISO 14971:2019 en EN ISO 15223-1:2016.

Almere, 21 November 2025



Lianda Mulder-Timmerman
Quality Assurance & Regulatory Affairs

De geldigheid van deze conformiteitsverklaring tezamen met de bijlage is gelijk aan de geldigheid van ons meest recente ISO 13485 certificaat, doch tot uiterlijk 31 december 2028.

The validity of this Declaration of Conformity together with the appendix is equal to the validity of our most recently issued ISO 13485 certificate, until December 31 2028 at the latest.

Medex Instrumenten Service is de handelsnaam van Medex FMT B.V.
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Medex Instrumenten Service

Bijlage van Verklaring
Appendix of the Declaration

De volgende productgroepen behoren tot deze conformiteitverklaring:
The following product groups are included to this Declaration of Conformity:

Product group	**Rule**	**CND**
Cutting instruments, Others	6	L0199
Dissectors, General surgery	6	L0315
Ear surgery instruments – Others	6	L140599
Elevators, Orthopaedic surgery	6	L0902
ENT instruments – Others	6	L1490
Forceps, General surgery	6	L0313
Forceps, Grasping	6	L031304
Forceps, Nasal and paranasal	6	L140202
Forceps, Tendons and ligamenta	6	L091305
General surgery instruments – Others	6	L0399
Gouges, orthopeadic surgery	6	L090403
Instruments for insertion and extractions of osteosynthesis devices	6	L091001
Larynx instruments	6	L1403
Microsurgical instruments – Others	6	L1099
Middle ear surgery instruments – Others	6	L14050199
Mini-Invasive surgery instruments – others	6	L1299
Nasal and paranasal surgery instruments – Others	6	L140299
Obstetrical and gynaecological instruments – Others	6	L059099
Orthopaedic burs, reusable	6	L0916
Orthopaedic instruments – Others	6	L0999
Orthopaedic prostheses reamers and burs	6	L091102
Orthopaedic surgery, chisels	6	L090402
Orthopaedic surgery, cutting instruments	6	L0909
Orthopaedic surgery, dilators and retractors	6	L0915
Orthopaedic surgery, elevators	6	L0902
Orthopaedic surgery, mallets	6	L0903
Orthopaedic surgery, osteotomes	6	L090401
Oropharynx instruments – others	6	L14010299
Osteosynthesis instruments, Reusable – Others	6	L091099

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Bijlage van Verklaring
Appendix of the Declaration

Vervolg van de productgroepen:
Continuation of product groups:

Product groups	**Rule**	**CND**
Pharynx instruments	6	L1401
Retractors, General surgery	6	L031401
Retractors, Hooks	6	L03140104
Retractors, Rectal and anal	6	L040902
Retractors, Self-retaining	6	L0314010
Reusable surgical instruments – Others	6	L9099
Scalpel handles	6	L010103
Scissors, Cast	6	L01040101
Spatulae, General surgery	6	L031402
Sternotomy instruments	6	L0804
Surgical cannulas – Others	6	L030199
Surgical cannulas, Aspiration and irrigation	6	L03010
Surgical cannulas, Aspiration and irrigation with finger cut off	6	L03010
Surgical knives	6	L0102
Surgical probes, Rectal	6	L04100202
Suture instruments – Others	6	L0299
Thoracic surgery instruments – Others	6	L0899
Tweezers, surgical and anatomic	6	L031308
Urological dilators	6	L060501
Urethral dilators	6	L06050101
Vaginal dilators	6	L0509020101
Venous strippers	6	L070804
Vascular tunnellers	6	L070805

REVISION
Medex Instrumenten Service is relocated to a new address per 21-11-2025. Due to this change, the address and date of signature in this declaration of conformity is updated.