

CERTIFICATE

Management System as per
ISO 13485 : 2016

The Certification Body TÜV NORD Brasil hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2016, that the organization

Kolplast CI Ltda
Estrada Municipal Benedito de Souza, 418 - Bairro da Mina
13299-364 - Itupeva - SP -
Brazil

with the locations according to the annex

operates a management system in accordance with the requirements of ISO 13485 : 2016 and will be assessed for conformity within the 3 years term of validity of the certificate.

Scope

Design, Development, Manufacture, Storage, Sales and Marketing and Distribution of Electric Examination Bed, Procedural Light Source, Fetal Monitor, Colposcope, Anesthesia Kit, Vaginal Speculum, Cervical Brush, Procedure Forceps, Hysterometer, Anuscope, Retosigmoidoscope, Dilator, Ayre Spatula, Procedure Gloves, Umbilical Clamp, Surgical Drape, Venous Dissector, Identification Bracelet, Punch, Nasal Speculum, Manual Vacuum Aspirator and Cannula, Slide Processor, Liquid Cytology Solutions and Supplies, In vitro Diagnostic Kits, Colpocytology Kit, Catheter Introduction Kit, IUD Insertion Kit, Suture Removal and Suture Kit, Surgical Gown, Kits for hospital procedures, Swabs, Saliva Collection Kits, Kits for Specimen collection and transport, Gel for Ultrasound and Import and marketing of Pessary, Ultrasound, Fetal Detector and Fetal Monitor.

Certificate Registration No. TNBR-25876
Audit Report - WO 24668

End of validity of the previous certificate: 2026-02-18
Valid from 2026-03-03
Valid until 2029-02-18
Initial Certification 2020



Certification Body
TÜV NORD Brasil



Barueri, 2026-03-03

The validity of this certificate is subject to the continuous and satisfactory compliance of the company to the conditions stated in the certification contract.

TÜV NORD Brasil Avaliações da Qualidade Ltda. Al. Madeira, 222 – 3º Andar – 06454-010 – Barueri – SP tuv-nord.com/br



Revisão	Data	Descrição
00	03/03/2026	Emissão inicial

ANNEX

to Certificate Registration No. TNBR-25876
ISO 13485 : 2016

Kolplast CI Ltda

Estrada Municipal Benedito de Souza, 418 - Bairro da Mina
13299-364 - Itupeva - SP - Brazil

Certificate-Registration- No.	Location	Scope
TNBR-25876-001	Kolplast CI Ltda Estrada Municipal Benedito de Souza, 418 Bairro da Mina - 13299-364 - Itupeva - SP - Brazil	Design, Development, Manufacture, Storage, Sales and Marketing and Distribution of Electric Examination Bed, Procedural Light Source, Fetal Monitor, Colposcope, Anesthesia Kit, Vaginal Speculum, Cervical Brush, Procedure Forceps, Hysterometer, Anuscope, Retosigmoidoscope, Dilator, Ayre Spatula, Procedure Gloves, Umbilical Clamp, Surgical Drape, Venous Dissector, Identification Bracelet, Punch, Nasal Speculum, Manual Vacuum Aspirator and Cannula, Slide Processor, Liquid Cytology Solutions and Supplies, In vitro Diagnostic Kits, Colpocytology Kit, Catheter Introduction Kit, IUD Insertion Kit, Suture Removal and Suture Kit, Surgical Gown, Kits for hospital procedures, Swabs, Saliva Collection Kits, Kits for Specimen collection and transport, Gel for Ultrasound and Import and marketing of Pessary, Ultrasound, Fetal Detector and Fetal Monitor.
TNBR-25876-002	Kolplast CI Ltda Estrada Municipal Benedito de Souza, 268 Bairro da Mina - 13299-364 - Itupeva - SP - Brazil	Receiving and storage of inputs of Electric Examination Bed, Procedural Light Source, Fetal Monitor, Fetal Detector, Colposcope, Anesthesia Kit, Vaginal Speculum, Cervical Brush, Procedure Forceps, Hysterometer, Anuscope, Retosigmoidoscope, Dilator, Ayre Spatula, Procedure Gloves, Umbilical Clamp, Surgical Drape, Venous Dissector, Identification Bracelet, Punch, Nasal Speculum, Manual Vacuum Aspirator and Cannula, Slide Processor, Liquid Cytology Solutions and Supplies, Kits for in vitro diagnostic use, Colpocytology Kit, Catheter Introduction Kit, IUD Insertion Kit, Suture Removal and Suture Kit, Surgical Gown, Kits for hospital procedures, Swabs, Saliva Collection Kits, Kits for Specimen collection and transport, Gel for Ultrasound and Pessary.
TNBR-25876-003	Kolplast CI Ltda Estada Municipal Benedito de Souza, 241 Galpão 2 - Bairro da Mina - 13299-364 - Itupeva - SP - Brazil	Storage and Distribution of Electric Examination Bed, Procedural Light Source, Fetal Monitor, Fetal Detector, Colposcope, Anesthesia Kit, Vaginal Speculum, Cervical Brush, Procedure Forceps, Hysterometer, Anuscope, Retosigmoidoscope, Dilator, Ayre Spatula, Procedure Gloves, Umbilical Clamp, Surgical Drape, Venous Dissector, Identification Bracelet, Punch, Nasal Speculum, Manual Vacuum Aspirator and Cannula, Slide Processor, Liquid Cytology Solutions and Supplies, Kits for in vitro diagnostic use, Colpocytology Kit, Catheter Introduction Kit, IUD Insertion Kit, Suture Removal and Suture Kit, Surgical Gown, Kits for hospital procedures, Swabs, Saliva Collection Kits, Kits for Specimen collection and transport, Gel for Ultrasound and Pessary.

End of the list

Barueri, 03/03/2026

This certification was conducted in accordance with the TÜV NORD Brasil auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Brasil Avaliações da Qualidade Ltda. Al. Madeira, 222 – 3º Andar – 06454-010 – Barueri – SP tuv-nord.com/br