

EU Declaration of Conformity

We as the manufacturer, MICROS Produktions- und Handelsges.m.b.H. with registered office in Hunnenbrunn - Gewerbezone 5, 9300 St. Veit an der Glan, Austria, hereby declare under our sole responsibility that the devices covered by this declaration comply with Regulation (EU) 2017/746, General Safety and Performance Requirements, and the relevant Union legislation.

SRN (Single Registration Number): AT-MF-000039061

Product category: Pathological Instruments
Product groups: Microtome Blades, Trimming Knives
Classification: Class A, rule 5 (acc. to Annex VIII of Regulation (EU) 2017/746)
EMDN code: W0202059085

Ref. No.	Basis UDI-DI	Product name	Product specifications
109214	9120131862146	MS22	Low Profile Disposable Microtome Blade, angle 22°
109206	9120131862061	MS33	Low Profile Disposable Microtome Blade, angle 30°
109207	9120131862078	MS24	Low Profile Disposable Microtome Blade, angle 35°
109211	9120131862115	MS200	Low Profile Disposable Microtome Blade, angle 35°
109212	9120131862122	MS300	Low Profile Disposable Microtome Blade, angle 35°
109213	9120131862139	HP	High Profile Disposable Microtome Blade, angle 35°
109220	9120131862207	130mm Trimming Knife	Sectioning of hard tissues with fibers, blade length 130mm
109221	9120131862214	260mm Trimming Knife	Sectioning of hard tissues with fibers, blade length 260mm

Intend of use: These disposable, non-sterile in vitro diagnostic devices for clinical use are intended for thin sectioning of tissue prepared for pathological examination.

EC regulation: Regulation (EU) 2017/746 (In Vitro Diagnostics Medical Devices)

Conf. Assessment Route: Annex II and Annex III of this Regulation

CH	REP	Biosystems Switzerland AG Hofackerstrasse 40A 4132 Muttenz, Switzerland
-----------	------------	-------------------------------------------------------------------------------

This declaration is effective for products placed on the market as of the date of issue. Any modification of the devices not authorized by MICROS Produktions- und Handelsges.m.b.H will invalidate this declaration.

St. Veit an der Glan, 26.02.2024



Herbert Luttenberger
Quality Manager & PRRC

MICROS Produktions- und Handelsges.m.b.H • Hunnenbrunn - Gewerbezone 5 • A-9300
St. Veit/Glan Telefon +43 4212 30901 • Fax +43 4212 30901-90 • E-Mail office@micros.at

Bank: Unicredit Bank Austria, **IBAN:** AT211100 0032 7004 6000, **BIC:** BKAUATWW
Firmenbuch-Nr.: FN75375x, **Gerichtsstand:** St. Veit/Glan, **UID:** ATU15049007, **EORI:** ATEOS1000002137

