DATA SHEET – STERILE SINGLE-USE GOUGE BLADES

MD Class IIa Medical Device

Gouge blade base UDI-Di code: 376024597GOUGEBLADES7X

Description: Sterile, single-use gouge blade intended exclusively for use by healthcare professionals trained in its use

Claimed Use: Excision of the stratum corneum of the skin in the treatment of epidermal conditions of the foot

Models: No. 1, No. 2, No. 3, No. 4, No. 5, No. 6, No. 8, No. 10, No. 12, No. 15.

Packaging: cardboard boxes containing 20, 50, 100, 250 or 500 units. Each blade is placed in an individual package maintaining its sterility.

Classification: Class IIa medical device (application of Rule 6 of Annex VIII to Regulation 2017/745 and Rule 6 of Annex IX to Directive 93/42/EEC consolidated).
Invasive, surgical-type device intended for temporary use.

Connection to other devices: In order to avoid injury, the blade must be held in place by a scalpel handle or a universal handle (round or ergonomic handle)

Materials used:
- Blade: X65Cr13 (6Cr13) grade stainless steel
- individual packaging: one side made of aluminium lamination + one side made of polyethylene (PE)
- Box: coated cardboard

Storage: Blades should be stored in a dry and ventilated place (Humidity ≤80%) and should not be mixed with corrosive, contaminated, or hazardous materials

Period of validity of sterility; 5 years

Description of the symbols on the packaging:

	EXPIRY DATE		CAREFUL!
LOT	LOT NUMBER		FEARS HUMIDITY
	DO NOT USE IF PACKAGING IS DAMAGED		STORE AWAY FROM SUNLIGHT
STERILE R	STERILIZED BY IRRADIATION		UNIQUE STERILE BARRIER SYSTEM
	DO NOT REUSE (SINGLE USE, USE ONLY ONCE)		RECYCLABLE PACKAGING
	MAKER		DISTRIBUTOR

MANUFACTURER: COBLENTZ MEDICAL BLADES INDUSTRY (CZ. M.B.I) – Le Courbet – 531 route du Bellay 49650 ALLONNES - S.A.S WITH A CAPITAL OF 10000 Euros – RCS ANGERS – SIREN N°: 810 823 492 – NEF: 2014Z
SRN NUMBER: FR-MF-000010361

CE MARKING: The device has been CE marked since 26/07/2016. It is currently covered by the CE certificate n°31689 Rev. 9, and its annex 38317 Rev. 0, issued by the GMED on 12/04/2021 and valid until 31/12/2028, taking into account the provisions of Article 120 of Regulation 2017/745 amended by Regulation 2023/607 of 15/03/2023.