



EC Declaration of Conformity

No:	EU-Gallant-01
Version:	01
Effective date:	07.12.2023

Manufacturer and address: Private Company «Galit»
6E, 15 Kvitnya St., Baikivtsi village, region Ternopil, 47711, Ukraine

Manufacturer's facility address: 1, Nova str. Plotycha village Ternopil, 47704, Ukraine

Medical Device: **Dental Unit «Gallant»**

S.n.	Name of products	Reference number
1.	Dental Unit Gallant Omnipratique, Model: FU	002.000.015
2.	Dental Unit Gallant Omnipratique, Model: FL	002.000.015
3.	Dental Unit Gallant Omnipratique, Model: HU	002.010.013
4.	Dental Unit Gallant Omnipratique, Model: HL	002.010.013
5.	Dental Unit Gallant Omnipratique Economic, Model: HU	002.010.020
6.	Dental Unit Gallant Omnipratique Economic, Model: HL	002.010.020
7.	Dental Unit Gallant Ambidextre, Model: Am U	002.010.012
8.	Dental Unit Gallant Ambidextre, Model: Am L	002.010.012
9.	Dental Unit Gallant PRO, Model: TU	002.010.008
10.	Dental Unit Gallant PRO, Model: TL	002.010.008
11.	Dental Unit Gallant PRO, Model: DU	002.000.008
12.	Dental Unit Gallant PRO, Model: DL	002.000.008
13.	Dental Unit Gallant Autonome, Model: AU	002.000.010
14.	Dental Unit Gallant Autonome, Model: AL	002.000.010
15.	Dental Unit Gallant Autonome Console, Model: ACU	002.000.013
16.	Dental Unit Gallant Autonome Console, Model: ACL	002.000.013
17.	Dental Unit Gallant Console, Model: CU	002.000.012
18.	Dental Unit Gallant Console, Model: CL	002.000.012
19.	Dental Unit Gallant Light, Model: LL	002.000.014
20.	Dental Unit Gallant Orhto, Model: O	002.010.016
21.	Dental Unit Gallant Cart-5, Model: K-5	002.020.013
22.	Dental Unit Gallant Cart-5 Telescopic, Model: K-5	002.020.013-02
23.	Dental Unit Gallant Cart-5 Autonome , Model: KA-5	002.020.015
24.	Dental Unit Gallant Cart-5 Autonome ASP, Model: KA-5	002.020.009

We declare in our sole responsibility that the above-mentioned products manufactured by us to which this statement refers, conform to the essential requirements according to the Annex I Directive 93/42/EEC amended by 2007/47/EC.

Technical documentation and standards applied are available on request.

Class according to Annex IX of the Directive 93/42/EEC:	IIa, Rule 9	
Conformity assessment procedure according to:	Annex II excluding section 4 of the Directive 93/42/EEC Full Quality Assurance System	
European Authorized Representative:	Company Name	Galdent CZ s.r.o.
	Address	K. Vapence, 448 41503 Teplice Czech Republic
	SRN number:	CZ-AR-000032813
Notified body	BSI NL	
Address of Notified body	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands; Identification number: 2797	
Certificate Number	CE 703906	
Start of CE-Marking	June 2019	

Date, Place
Name, Position, Signature

07.12.2023, Ternopil
Volodymyr Zolotyy, Director

