

Repertorio Dispositivi Medici

HelpDesk LogOut Italian English

Company's Data

Off Line Signature

Class I, II a /b, III Medical Devices

Medical Device (DM)

- -General data -Data sheet -Documentation
- -Commercial Data
- -Any other DM needed for the functioning
- Systems or Assembled Kits (c.2 Art.12)
- Activity in progress
- ▶ EC certificates
- **▶** Deposit
- Data Transmission
- ▶ Entered DMs data
- Documentation

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Browsing General data

General data

*Trade name and model: ECOLYT SG 100

*Code assigned by the manufacturer (catalogue | 910.00.030; 910.00.029

Regulation on prosthetic assistance payable under the National Health Service: Payment conditions and rates:

*User role as to the DM: ALTRO SOGGETTO DELEGATO DAL FABBRICANTE

Company that entered the DM: MDSS GMBH

Detail

*Manufacturer: GRAMM TECHNIK GMBH
Detail

Agent: Detail

Marketing Responsible:

System progressive attributed to DM: 94260/R Was it ever notified to the M.D.S.as provided for

by the procedure prescribed before the enforcement of D.M.20/02/07 or under the

present procedure?

yes 🔾

Classification

If the declarant does not have the GMDN code can choose the option 'ND' that means GMDN not declared, and proceed with the compilation of next data. Indication of the GMDN code is essential in order to send the information to the European database EUDAMED.

*Complete GMDN repertoire: 35858 - A CASTING ALLOY SUITABLE FOR THE FABRICATION OF DENTAL

*CND classifications: Q010601 - LEGHE PER USO ODONTOIATRICO

Certifications

*EC Classification (D.L.46/97 implementation Dir.CE 93/42, D.L.vo 507/92 implementation Dir.CE 90/385) :

Annex according to which the device was

lasse IIa

Annex II/2 Annex III/3

Annex IV/4

Annex V/5 Annex VI

Annex VII

No.of certificate of the EC marking	Certificate Expiration Date	Notified Body Code-Name	Details of Community harmonized standards and of national transposing rules that may be applied	EC Directive 2003/32	File containing the certificate
0021.03.21/20	14/04/2017	0483 - MDC MEDICAL DEVICE CERTIFICATION GMBH		THE CERTIFICATE DOES NOT CONCERN THE EC DIRECTIVE 2003/32	EG- ZERTIFIKAT D.PD

Link with other DMs

The DM, to perform its function, needs other DM: yes no

If the answer is affirmative, the other DMs need to be indicated through the function "Any other DM needed for the functioning". Other eventual DM needed for the operation.