

ASIGA Pty Ltd.**SRN:**
AU-MF-000012099**FORM**
List of CE Marked Products (MDR)
(Annex Ia of the Authorized Representative Agreement)**MTPC DOC. No.:**
Revision 01
Valid from 06.07

Last update of the list: 2023-07-19					Current number of categories:			Number of categories defined in agreeme		
New products are marked in green / Obsolete products in red					1			1		
Internal Adm.- No.AR	Registration Number German CA: DE/CA70/...	Registration Number EUDAMED	Cataloge No.	Product name (Model name)	Indications (Intended use)	BASIC UDI-DI	EMDN- Code	Nomenclature Description (Product category)	Class / Rule	Declaration of Conformity Date
To be filled by MTPC	To be filled by MTPC									
ASI-01-MDR	DE/CA70/00188692	//	04504	DentaGUIDE	Asiga DentaGUIDE is intended exclusively for professional dental work. Asiga DentaGUIDE is a 3D print resin intended for the manufacturing of 3D printed dental surgical guides. Asiga DentaGUIDE is not intended for long term use (longer than 30 days) within the oral cavity. The surgical guides produced are suitable for all dental indications including dental implant surgical guides, crown and bridges applications.	93592150RE SINSUW	Q01020501 99	DENTAL, OPHTHALMOLO GIC AND ENT DEVICES,DENT ISTRY RESINS - OTHER	Class I Rule 1	09.05.2023
ASI-01-01-MDR	DE/CA70/00188692	//	05165	DentaTRAY	Asiga DentaTRAY is intended exclusively for professional dental work. Asiga DentaTRAY is a 3D print resin intended for the manufacturing of 3D printed custom dental trays. Asiga DentaTRAY is not intended for long term use (longer than 30 days) within the oral cavity. The custom dental trays produced are suitable for all dental indications including crown and bridge, dentures, orthodontics, and thermoforming applications.	93592150RE SINSUW	Q01020501 99	DENTAL, OPHTHALMOLO GIC AND ENT DEVICES,DENT ISTRY RESINS - OTHER	Class I Rule 1	09.05.2023
ASI-01-02-MDR	DE/CA70/00188692	//	03768	DentaTRY A1	Asiga DentaTRY is intended exclusively for professional dental work. Asiga DentaTRY is a 3D print resin intended for the manufacturing of 3D printed denture try-in models. Asiga DentaTRY is not intended for long term use (longer than 30 days) within the oral cavity. The denture try-in models produced are suitable for dental indications including dentures try-ins, custom trays, study models, and thermoforming applications.	93592150RE SINSUW	Q01020501 99	DENTAL, OPHTHALMOLO GIC AND ENT DEVICES,DENT ISTRY RESINS - OTHER	Class I Rule 1	09.05.2023
			03817	DentaTRY A2						
			03819	DentaTRY A3						
			03821	DentaTRY B1						
			03823	DentaTRY B2						
			03825	DentaTRY B3						
ASI-01-03-MDR	DE/CA70/00188692	//	03746	DentaIBT	Asiga DentaIBT is intended exclusively for professional dental work. Asiga DentaIBT is a 3D print resin intended for the manufacturing of 3D printed indirect bonding trays. The indirect bonding trays produced are suitable for dental indications including orthodontic indirect bonding trays.	93592150RE SINSUW	Q01020501 99	DENTAL, OPHTHALMOLO GIC AND ENT DEVICES,DENT ISTRY RESINS - OTHER	Class I Rule 1	30.05.2023

Internal Adm.- No.AR	Registration Number German CA: DE/CA70/...	Registration Number EUDAMED	Cataloge No.	Product name (Model name)	Indications (Intended use)	BASIC UDI-DI	EMDN- Code	Nomenclature Description (Product category)	Class / Rule	Declaration of Conformity Date


Remarks:

- Each product or model name and all variants of the product has to be described.
- Item.-No. are indicated individually but not as a product group,
- Please indicate product application

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Released:Legal manufacturer2023-07-21

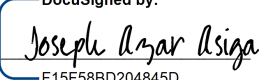
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Joseph Azar Asiga