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eIFU Readiness Index 2026

EUDAMED registration and electronic instructions for use (eIFU) readiness of medical device manufacturers: Türkiye, the European Union and the world

32,580
MANUFACTURERS

1.11 million
DEVICE MODELS

95
COUNTRIES

Data as of: 13 October 2026 · Published: 18 October 2026 · Kardan Digital

About this report

This report uses public data from EUDAMED, the European Commission's medical device database, to measure how manufacturers have registered their devices and whether they have declared an electronic instructions for use (eIFU) link for them. EUDAMED became mandatory on 28 May 2026; devices already on the market must be registered by 28 November 2026. The report shows where the industry stands between these two dates, comparing Türkiye, the European Union and manufacturer countries outside the EU.

Scope

- EUDAMED actor registrations in all countries (manufacturers, importers, authorised representatives)
- Latest-version device registrations of manufacturers (Basic UDI-DI and UDI-DI)
- The eIFU link in device records ("additional information URL")
- Company-by-company scan in Türkiye, random model samples elsewhere

Citation

eIFU.one Research (2026). eIFU Readiness Index 2026, Edition 3. Kardan Digital. eifu.one

Edition note

Edition 3 (18 October 2026): the Türkiye scan was extended; models in the rate rose from 10,854 to 82,056. The share of models with an eIFU link moved from 17.3% to 17.2%, and the confidence interval narrowed from ±0.4 to ±0.1 points. Companies with a partly ready eIFU rose from 37 to 44; companies with unknown status fell from 11 to 6. Edition 2 (14 October 2026) corrected confidence intervals for clustering by manufacturer and added non-EU countries.

Disclaimer

This report is for information only and is not legal advice. Data were taken from EUDAMED's public interfaces on the stated date; errors and gaps in EUDAMED records may carry over. The report contains no company names; all results are aggregate statistics. A device without an eIFU link in EUDAMED may still have an eIFU.

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Executive summary

KEY FINDINGS

17%
Only 17% of the device models Turkish manufacturers have on the market carry an eIFU link in EUDAMED. The EU-27 average is 25%.

0.1%
Almost no link leads to the device itself. Links that take the user straight to the device's instructions: 0.1% in Türkiye, 2.2% in the EU-27.

10.7%
Of the 1,508 new MDR/IVDR models registered after 28 May, only 10.7% have an eIFU link.

52%
577 of the 1,109 Turkish manufacturers registered in EUDAMED have no device on the market. The 28 November deadline concerns part of them directly.

136,589
Türkiye has more device models on the market than Germany (132,779). 97% of them are legacy devices.

1.5%
The global picture is uneven: the eIFU rate is 1.5% in China and 30% in the US; the non-EU average is 16%.

THREE STEPS FOR MANUFACTURERS

1. **Give every device its own address.** Declare a persistent eIFU address in EUDAMED for every UDI-DI that takes the user straight to that device's instructions. GS1 Digital Link (/01/GTIN) makes this standard.
2. **Complete registration and link together.** When registering legacy devices before 28 November 2026, fill in the eIFU field as well, so no second update round is needed.
3. **Make sure updates reach the user.** When instructions change, track that the right version reaches users in the field. This is the information most often lost with printed instructions.

1. Regulatory timeline

EUDAMED's actor, UDI/device, certificate and market surveillance modules have been mandatory since 28 May 2026. Devices placed on the market before that date and still supplied must be registered by 28 November 2026. On the eIFU side, Implementing Regulation (EU) 2025/1234 opened electronic instructions to almost all devices for professional use. The "additional information URL" in EUDAMED is the link the manufacturer declares for the device; the eIFU rates in this report measure this field.

FIGURE 1

The industry is in the final months between the mandate and the registration deadline

41 days — time left to the 28 November 2026 registration deadline (as of 18 October 2026)

16 July 2025	●	**Implementing Reg. 2025/1234** eIFU extended to devices for professional use
27 November 2025	●	**Decision 2025/2371** Six-month transition starts
28 May 2026	●	**EUDAMED mandatory** Actor, UDI/device, certificate, market surveillance modules
28 November 2026	●	**Registration deadline** EUDAMED registration of devices on the market[1]

Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

[1] Some sources give 27 November 2026 (12 months from publication); Commission guidance says 28 November.

2. Türkiye

541 of the 1,109 registered Turkish manufacturers have at least one device in EUDAMED. Their 136,589 device models on the market exceed those of any EU country. Most of them, however, are certified under the old directives: the MDR/IVDR transition and EUDAMED registration fall into the same period.

FIGURE 2

1,866 Turkish actors are registered in EUDAMED; 1,109 are manufacturers



Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

FIGURE 3

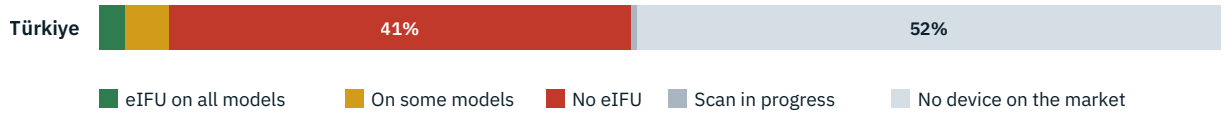
97% of the 136,589 models on the market are certified under the old directives



Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

FIGURE 4

Most Turkish manufacturers with devices have no eIFU link; 577 have no device on the market



Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.
Company status is computed from scanned models.

3. Registrations after May and readiness for 28 November

FIGURE 5

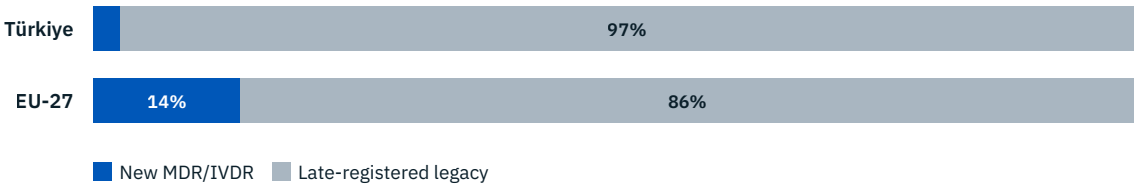
43% of models on the market in Türkiye and 61% in the EU-27 were registered or updated after 28 May



Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

FIGURE 6

Türkiye has 1,508 new MDR/IVDR models and 56,737 late-registered legacy models since 28 May



Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

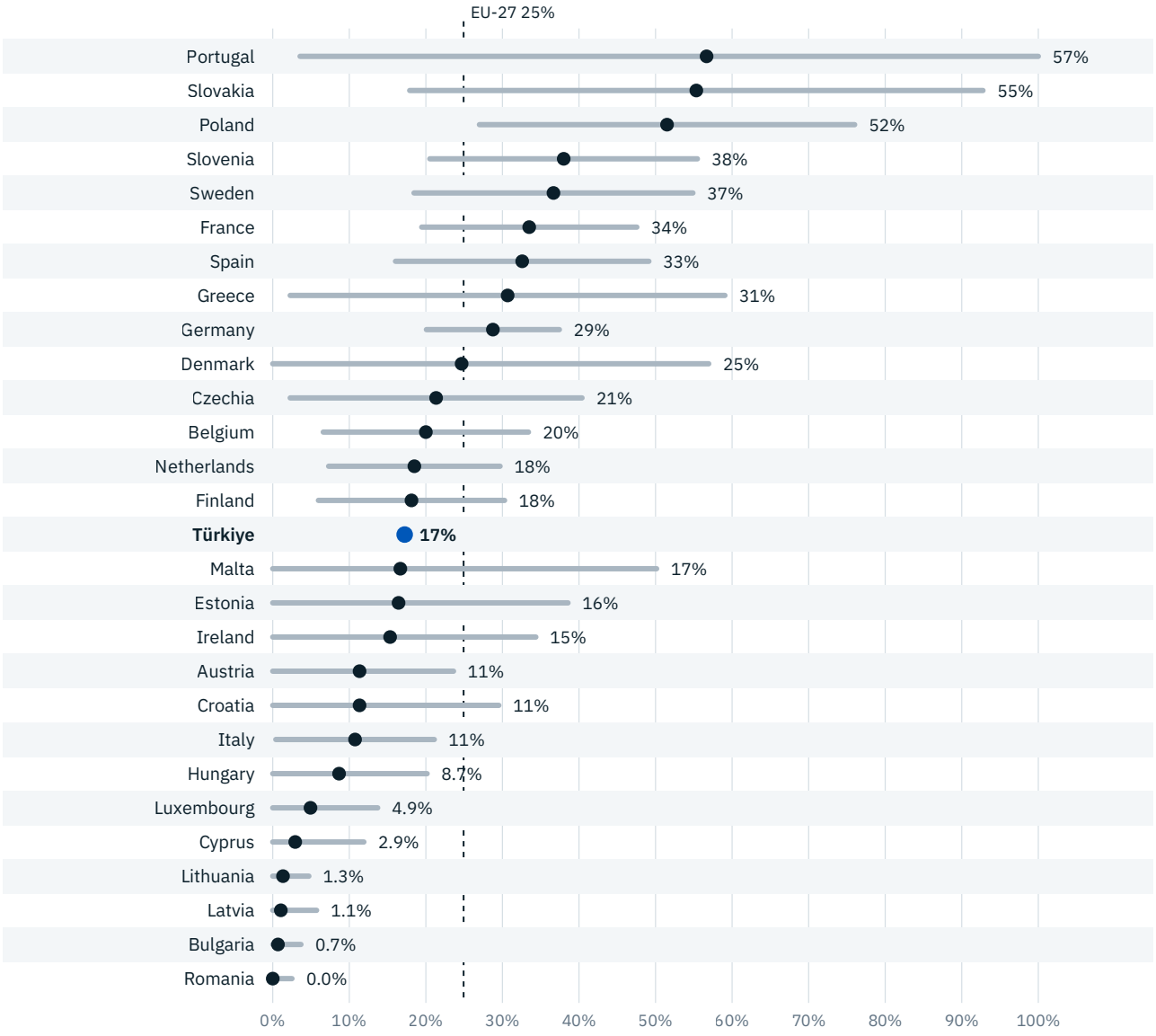
All new registrations were scanned: 10.7% of the 1,508 new models have an eIFU link. Even for new MDR/IVDR devices, the eIFU field is mostly left empty. The large number of late-registered legacy models suggests that companies are focusing on the registration duty and leaving the eIFU link for later.

4. European and global comparison

The spread within the EU-27 is wide. Among countries with at least 20 sampled companies, the rate is highest in Portugal, Slovakia, Poland and lowest in Austria, Italy, Hungary. Türkiye's rate lies below the confidence interval of the EU-27 average. Outside the EU the picture is uneven too; in China, which registers the most device models, the rate is very low.

FIGURE 7

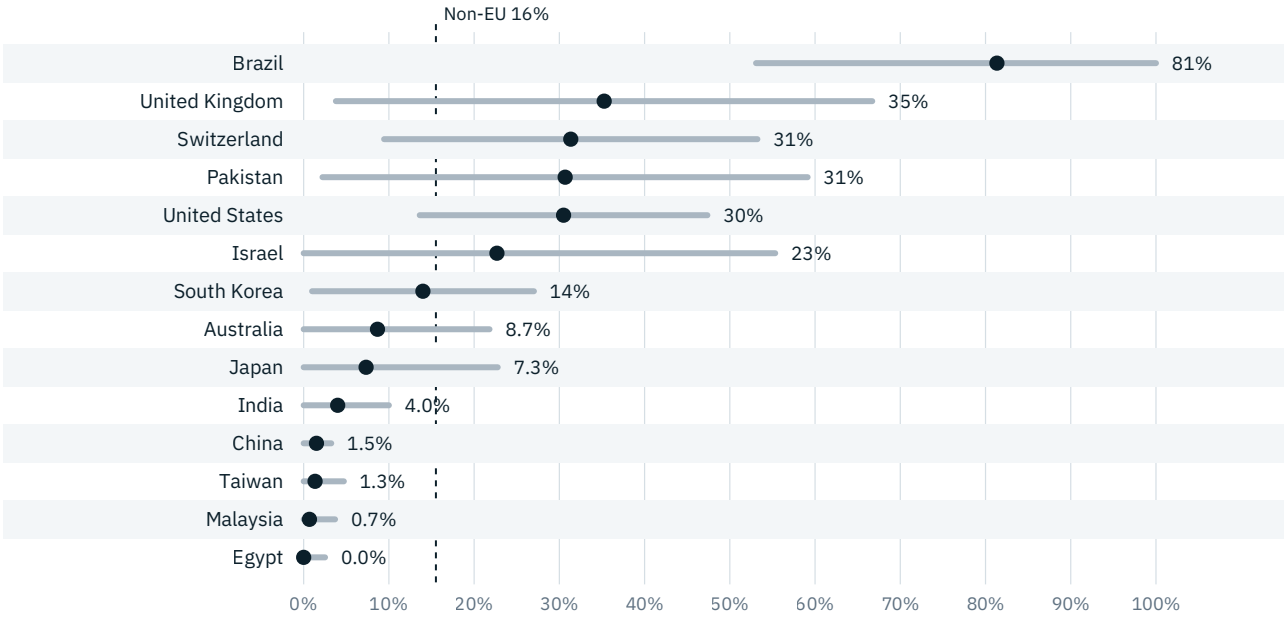
Türkiye (17%) trails the EU-27 average (25%)



Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

FIGURE 8

The non-EU average is 16%; in China, the country with the most models, it is 1.5%



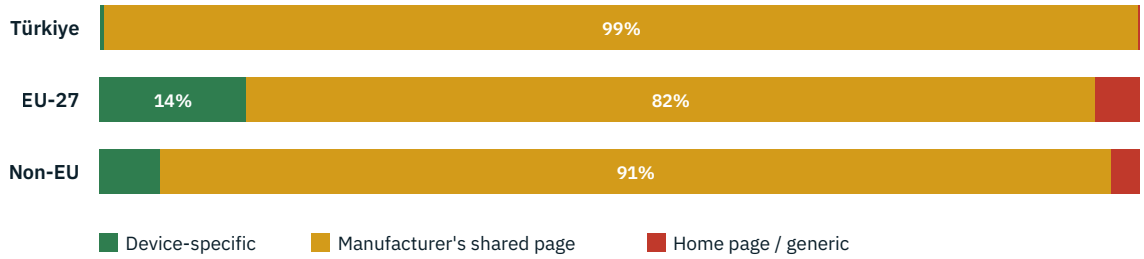
Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

Lines show 95% confidence intervals; they are wide where a few companies dominate.

5. Does the eIFU link lead to the device?

FIGURE 9

Most eIFU links lead to the manufacturer's shared page



Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

To detect shared addresses, one more model from the same manufacturer was scanned for every linked model in the samples.

The eIFU field in EUDAMED is mostly filled with a single IFU / download page for all of a manufacturer's products, or with its home page. A shared portal may well be compliant; users can search for the device there. But only a device-specific address takes a user from the code on the device straight to the right instructions.

Appendix A — Country tables

TABLE A1 **Türkiye and EU-27 countries**

Country	Manufacturers	With devices	Device models	Legacy	New after May	With eIFU (95% CI)	Device-specific	Sampled companies
Türkiye	**1,109**	**541**	**136,654**	**97%**	**1,508**	**17% (17%–17%)**	**0.1%**	**467**
Germany	3,710	1,894	135,174	84%	10,578	29% (20%–37%)	2.2%	184
Italy	2,780	1,363	73,342	84%	5,153	11% (0%–21%)	0.8%	137
France	1,824	942	28,762	73%	2,489	34% (19%–48%)	2.8%	136
Poland	815	439	15,520	68%	1,923	52% (27%–76%)	3.5%	89
Spain	816	475	10,683	60%	1,361	33% (16%–49%)	4.5%	124
Czechia	353	197	10,612	81%	953	21% (2%–40%)	2.0%	45
Netherlands	1,100	502	8,450	71%	702	18% (7%–30%)	4.5%	102
Belgium	378	194	7,232	85%	446	20% (7%–33%)	4.7%	39
Portugal	238	102	6,689	88%	377	57% (4%–100%)	0.0%	20
Romania	195	85	5,680	58%	52	0.0% (0.0%–2.5%)	0.0%	8
Finland	341	259	5,078	67%	92	18% (6%–30%)	1.3%	46
Denmark	405	207	4,894	68%	472	25% (0%–57%)	6.0%	36
Ireland	187	110	4,646	53%	318	15% (0%–34%)	2.0%	26
Austria	291	157	4,285	82%	338	11% (0%–24%)	1.3%	39
Sweden	661	385	4,207	31%	874	37% (18%–55%)	8.0%	67
Hungary	251	99	3,854	82%	257	8.7% (0.0%–20.2%)	0.0%	25
Greece	128	72	2,063	42%	185	31% (2%–59%)	13%	35
Slovakia	101	56	1,813	28%	628	55% (18%–93%)	0.7%	29
Lithuania	63	38	1,638	81%	111	1.3% (0.0%–4.7%)	0.7%	8
Croatia	57	30	1,034	81%	51	11% (0%–30%)	0.7%	18
Bulgaria	54	22	455	8%	139	0.7% (0.0%–3.7%)	0.0%	19
Slovenia	89	44	189	13%	45	38% (21%–55%)	16%	37
Estonia	46	20	180	55%	7	16% (0%–39%)	12%	20
Latvia	32	15	96	5%	15	1.1% (0.0%–5.7%)	0.0%	15
Cyprus	18	3	68	1%	5	2.9% (0.0%–11.9%)	0.0%	3
Luxembourg	19	6	61	54%	8	4.9% (0.0%–13.7%)	1.6%	6
Malta	16	6	12	17%	0	17% (0%–50%)	0.0%	6
EU-27	**14,968**	**7,722**	**336,717**	**79%**	**27,579**	**25% (20%–30%)**	**2.2%**	

Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

TABLE A2 Non-EU countries: top 30 by device models (at least 3 manufacturers with devices); total row covers 66 countries

Country	Manufacturers	With devices	Device models	Legacy	New after May	With eIFU (95% CI)	Device-specific	Sampled companies
China	7,539	4,719	223,820	82%	10,848	1.5% (0.0%–3.2%)	0.0%	191
United States	2,522	1,486	124,024	86%	7,174	30% (14%–47%)	1.8%	130
Japan	265	176	66,851	97%	620	7.3% (0.0%–22.8%)	0.0%	16
South Korea	1,002	552	66,166	97%	931	14% (1%–27%)	0.5%	68
United Kingdom	1,081	665	42,069	88%	1,815	35% (4%–67%)	2.0%	80
Pakistan	546	157	26,384	59%	1,421	31% (2%–59%)	0.0%	38
India	509	247	24,666	92%	555	4.0% (0.0%–10.0%)	0.7%	32
Switzerland	545	346	18,829	78%	1,792	31% (9%–53%)	0.7%	37
Taiwan	412	254	10,098	86%	477	1.3% (0.0%–4.7%)	0.0%	34
Brazil	83	42	8,748	96%	158	81% (53%–100%)	1.3%	14
Israel	395	212	6,704	45%	260	23% (0%–55%)	1.3%	26
Malaysia	160	73	3,208	90%	147	0.7% (0.0%–3.7%)	0.0%	19
Egypt	69	26	3,100	61%	205	0.0% (0.0%–2.5%)	0.0%	10
Australia	177	100	2,553	86%	142	8.7% (0.0%–21.8%)	0.7%	25
Singapore	93	53	2,156	85%	59	14% (0%–37%)	4.0%	15
Serbia	36	23	1,952	98%	12	0.0% (0.0%–2.5%)	0.0%	10
Canada	237	138	1,825	61%	201	34% (11%–57%)	5.3%	51
Mexico	16	7	676	95%	14	90% (68%–100%)	0.0%	5
Norway	141	86	590	34%	121	13% (2%–25%)	6.0%	42
Hong Kong	87	53	582	58%	86	0.7% (0.0%–3.7%)	0.0%	29
Argentina	25	17	514	88%	11	48% (0%–100%)	0.0%	11
Tunisia	12	6	512	95%	6	0.7% (0.0%–3.7%)	0.0%	4
Iran	38	30	332	49%	6	0.0% (0.0%–2.5%)	0.0%	24
Colombia	4	3	312	17%	0	20% (0%–72%)	0.0%	3
Saudi Arabia	14	6	290	0%	142	0.0% (0.0%–2.6%)	0.0%	2
New Zealand	30	21	280	39%	67	30% (0%–68%)	4.0%	20
Thailand	59	26	190	63%	20	2.7% (0.0%–6.9%)	0.7%	22
South Africa	36	17	184	72%	9	56% (9%–100%)	0.7%	15
Liechtenstein	17	12	152	13%	71	17% (0%–37%)	0.0%	12
Ukraine	23	11	138	9%	105	4.3% (0.0%–12.2%)	0.0%	11
Non-EU	**16,451**	**9,695**	**639,761**	**85%**	**27,695**	**16% (11%–20%)**	**0.7%**	

Source: EUDAMED (European Commission) public API and Data Lake, 13 October 2026; eIFU.one Research analysis.

Appendix B — Method and limitations

1. Only the latest version of each record is counted; earlier versions of the same device are excluded.
2. Device model = Basic UDI-DI, product variant = UDI-DI. Rates are at model level.
3. Company counts use the manufacturer role; importers and authorised representatives are shown separately.
4. "On the market" = EUDAMED status "On the EU market".
5. The eIFU link is EUDAMED's "additional information URL" field, read from one variant of each model.
6. Türkiye: 83,565 of 136,589 models on the market (61%) were scanned, in random order within each company: all or nearly all models for small and mid-sized portfolios, about 1,600 models per company for the largest. The rate is stratified by company (each company's rate weighted by its models on the market); sampling in the largest portfolios is reflected in the confidence interval.
7. Other countries: random model sample; 400 models in the 10 countries with the most manufacturers, 150 elsewhere. EU-27 and non-EU totals are averages of country rates weighted by models on the market.
8. Confidence intervals account for clustering by manufacturer: models of the same company often share one eIFU page, so intervals are wide where a few companies dominate.
9. "New after May" = MDR/IVDR model first registered in EUDAMED after 28 May 2026. EUDAMED has no placing-on-the-market date; late-registered legacy devices are counted separately.
10. eIFU link type: links whose address contains the device identifier or lead to a single product page are "device-specific"; addresses identical across several of a manufacturer's models are "shared"; home pages or generic IFU paths are "generic". A shared eIFU portal may well be compliant.
11. Dates come from the timestamp in the EUDAMED record identifier (ULID). The date an eIFU link was added is not recorded.

Appendix C — Abbreviations

Basic UDI-DI	Base identifier of a device model
CI	Confidence interval (95%)
eIFU	Electronic instructions for use
EU-27	The 27 EU member states
EUDAMED	European database on medical devices
IVD	In vitro diagnostic device
IVDD / IVDR	In vitro diagnostic directive / regulation
Legacy	Device certified under the old directives
MDD / MDR	Medical device directive / regulation
SRN	EUDAMED single registration number
UDI-DI	Device identifier of a product / package variant



eIFU.one

About eIFU.one

eIFU.one is a platform that lets medical device manufacturers publish electronic instructions for use at a persistent address for every device (GS1 Digital Link), make sure updates reach users in the field and stay consistent with their EUDAMED records. It is developed by Kardan Digital.

This report is updated in editions. As the scan of Türkiye completes, company-level results will firm up in the next edition.

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