

ELI VASTAVUSDEKLARATSIOON

Ettevõtte GIMA S.P.A. (Kordumatu registreerimisnumber (SRN): IT-MF-000011004),
põhitegevuskoht Gessate (MI), Via Marconi 1, registreeritud asukoht Milano, Via
Tommaso Grossi 2, meditsiiniseade tootjana:

Toote nimetus ja kaubanimi	Tootekood	Põhi-UDI-DI
STETO PINARD ALUMIINIUM	32505	8023279000U1090995600020L3
DUOFONO PEDIAATRILINE "WAN PLUS" – must	32506	80232790000C900526BB000N3
FONENDOSKOOP VASTSÜNDINUD WAN – punane	32508	80232790000C900527AA000MW
FONENDOSKOOP VASTSÜNDINUD WAN – hall	32509	80232790000C900527AA000MW
DUOFONO PEDIAATRILINE "WAN PLUS" – roosa	32511	80232790000C900526BB000N3
DUOFONO PEDIAATRILINE "CLASSIC" – helesinine	32512	80232790000C900526BB000N3
DUOFONO PEDIAATRILINE "WAN" – helesinine	32513	80232790000C900526BB000N3
DUOFONO PEDIAATRILINE "WAN" – punane	32515	80232790000C900526BB000N3
DUOFONO PEDIAATRILINE "CLASSIC" – must	32516	80232790000C900526BB000N3
STETOSKOOP LINUX – sinine	32518	80232790000C900556CC000Q8
STETOSKOOP LINUX – must	32524	80232790000C900556CC000Q8
FONENDO REGALITE – personaliseeritud	32525	80232790000C90052700000CW
FONENDO REGALITE DELUXE	32526	80232790000C900527CC000P2
STETOSKOOP LINUX – punane	32529	80232790000C900556CC000Q8
DUOFONO "CLASSIC" – tumeroheline	32531	80232790000C900526CC000NM
DUOFONO "CLASSIC" – oranž	32532	80232790000C900526CC000NM
DUOFONO "CLASSIC" – helesinine	32533	80232790000C900526CC000NM
DUOFONO "CLASSIC" – must	32534	80232790000C900526CC000NM
DUOFONO "CLASSIC" – bordeaux	32535	80232790000C900526CC000NM
DUOFONO "CLASSIC" – sinine	32536	80232790000C900526CC000NM
DUOFONO "CLASSIC" – roheline	32537	80232790000C900526CC000NM
DUOFONO "CLASSIC" – punane	32538	80232790000C900526CC000NM
DUOFONO "CLASSIC" – roosa	32539	80232790000C900526CC000NM
DUOFONO "CLASSIC" – royal sinine	32540	80232790000C900526CC000NM
DUOFONO "CLASSIC" – lilla	32541	80232790000C900526CC000NM
DUOFONO DIDATTICO – must	32542	80232790000C900526CC000NM
DUOFONO "CLASSIC CARDIOLOGICO" – sinine	32550	80232790000C90052602000CX
DUOFONO "CLASSIC CARDIOLOGICO" – bordeaux	32551	80232790000C90052602000CX
DUOFONO "CLASSIC CARDIOLOGICO" – must	32552	80232790000C90052602000CX
DUOFONO "TRAD PEDIAATRILINE" – must	32555	80232790000C900526BB000N3
FONENDO "TRAD PEDIAATRILINE" – roosa	32557	80232790000C900527BB000NG
FONENDO "TRAD" – tumeroheline	32558	80232790000C900527CC000P2
FONENDO "TRAD PEDIAATRILINE" – helesinine	32559	80232790000C900527BB000NG
FONENDO "TRAD" – must	32560	80232790000C900527CC000P2
FONENDO "TRAD" – punane	32561	80232790000C900527CC000P2
FONENDO "TRAD" – sinine	32562	80232790000C900527CC000P2
FONENDO "TRAD" – kollane	32563	80232790000C900527CC000P2
FONENDO "TRAD" – lilla	32564	80232790000C900527CC000P2
DUOFONO "TRAD" – must	32565	80232790000C900526CC000NM

DUOFONO "TRAD" – punane	32566	80232790000C900526CC000NM
DUOFONO "TRAD" – sinine	32567	80232790000C900526CC000NM
DUOFONO "TRAD" – tumeroheline	32568	80232790000C900526CC000NM
FONENDO "WAN" – must	32569	80232790000C900527CC000P2
FONENDO "WAN" – sinine	32570	80232790000C900527CC000P2
FONENDO "WAN" – bordeaux	32571	80232790000C900527CC000P2
FONENDO "WAN" – oranž	32572	80232790000C900527CC000P2
DUOFONO "WAN" – must	32574	80232790000C900526CC000NM
DUOFONO "WAN" – sinine	32575	80232790000C900526CC000NM
DUOFONO "WAN" – bordeaux	32576	80232790000C900526CC000NM
DUOFONO "WAN" – oranž	32577	80232790000C900526CC000NM
DUOFONO "JOTARAP" – lilla	32579	80232790000C900526CC000NM
DUOFONO "JOTARAP" – must	32580	80232790000C900526CC000NM
DUOFONO "JOTARAP" – sinine	32581	80232790000C900526CC000NM
DUOFONO "JOTARAP" – oranž	32582	80232790000C900526CC000NM
DUOFONO "JOTARAP" – roheline	32583	80232790000C900526CC000NM
DUOFONO "JOTARAP" – kollane	32584	80232790000C900526CC000NM
DUOFONO "JOTARAP" – helesinine	32585	80232790000C900526CC000NM
DUOFONO "JOTARAP" – fuksia	32586	80232790000C900526CC000NM
DUOFONO "JOTARAP" – läbipaistev roosa	32587	80232790000C900526CC000NM
FONENDOSKOOP YTON – tumeroheline	49500	80232790000C90052700000CW
FONENDOSKOOP YTON – tumesinine	49501	80232790000C90052700000CW
FONENDOSKOOP YTON – punane	49502	80232790000C90052700000CW
FONENDOSKOOP YTON – veesinine	49503	80232790000C90052700000CW
DUOFONO YTON – tumeroheline	49510	80232790000C90052600000CH
DUOFONO YTON – tumesinine	49511	80232790000C90052600000CH
DUOFONO YTON – punane	49512	80232790000C90052600000CH
DUOFONO YTON – veesinine	49513	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – must	49550	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – meresinine	49551	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – bordeaux	49552	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – türkiissinine	49553	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – hall	49554	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – tumeroheline	49555	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – punane	49556	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – litritega	49563	80232790000C90052600000CH
DUOFONO EVOLVE – sädelev pea – litritega	49564	80232790000C90052600000CH
DUOFONO EVOLVE – must pea – must	49567	80232790000C90052600000CH
DUOFONO EVOLVE – must pea – helesinine Caraibi	49568	80232790000C90052600000CH
DUOFONO EVOLVE – must pea – smaragdroheline	49569	80232790000C90052600000CH
DUOFONO EVOLVE – must pea – šokolaad	49570	80232790000C90052600000CH
DUOFONO EVOLVE – värviline pea – ploom	49574	80232790000C90052600000CH
DUOFONO EVOLVE – värviline pea – must	49575	80232790000C90052600000CH
DUOFONO EVOLVE – roosa/kuldne pea – valge	49578	80232790000C90052600000CH
FONENDO TRAD VÄRVITUD – must	51000	80232790000C900527CC000P2
FONENDO TRAD VÄRVITUD – punane	51001	80232790000C900527CC000P2

FONENDO TRAD VÄRVITUD – sinine	51002	80232790000C900527CC000P2
FONENDO TRAD VÄRVITUD – kollane	51003	80232790000C900527CC000P2
FONENDO TRAD VÄRVITUD – roheline	51004	80232790000C900527CC000P2
DUOFONO TRAD VÄRVITUD – must	51010	80232790000C900526CC000NM
DUOFONO TRAD VÄRVITUD – punane	51011	80232790000C900526CC000NM
DUOFONO TRAD VÄRVITUD – sinine	51012	80232790000C900526CC000NM

sihtotstarve: Mõeldud rindkere (südame ja kopsude) ja siseelundite auskultatsiooniks, et spetsialist saaks hinnata inimkeha teatud funktsioone ja tegevusi patoloogiate diagnoosimiseks,

I ohuklass (mittesteriilne), kooskõlas Määrus (EL) 2017/745 (MDR) VIII lisas sätestatud reegel 1, kinnitab ainuvastutusel, et toks seadme:

- vastab Määrus (EL) 2017/745 (MDR);
- nimetatud meditsiiniseade nõuetele vastamiseks pole kasutatud ühtseid kirjeldusi.

Gessate, 17/10/2025

GIMA S.p.A.

Seaduslik esindaja
(Nicola Manzoni)

