

Declaration of Conformity

Manufacturer: KameManNen Co., Ltd.
Address: 1-10-12 Yanagimachi, Sabae City, Fukui 916-0047 Japan

Authorised Representative: KameManNen Europe AB
Address: Stockholm SWEDEN

Product(s): [1] Metal spectacle frames without lenses
[2] Metal and plastic spectacle frames without lenses

Basic UDI-DI See attachment on next page.

Model No.: See attachment on next page.

Intended Purpose To hold a pair of lenses in order to correct the visual acuity of patients who need their vision corrected.

Classification (MDR, Annex VIII): Class I (Rule 1)
Conformity Assessment Procedure: Article 52 (7) of Regulation (EU) 2017/745
Applied Common Specification: N/A

We herewith declare that the above mentioned product(s) meets the provisions of the Regulation (EU) 2017/745 for medical device.
All supporting documentation is retained under the premises of the manufacturer.

Notified Body: N/A (not involved)

EU Quality Management System Certificate: N/A

Place: 1-10-12 Yanagimachi, Sabae City,
Fukui 916-0047 Japan

Date: 01 / 12 / 2024

Signature:

代表取締役 土山博史

Hiroshi Tsuchiyama
President





Model List

Model Number	Basic UDI-DI
01TR	457150646FRALLMD6
22	457150646FRALLMD6
33	457150646FRMEPLEZ
48	457150646FRALLMD6
49	457150646FRALLMD6
53	457150646FRALLMD6
54	457150646FRALLMD6
54W	457150646FRALLMD6
77	457150646FRMEPLEZ
90	457150646FRALLMD6
99	457150646FRALLMD6
101	457150646FRMEPLEZ
102	457150646FRALLMD6
103	457150646FRMEPLEZ
109	457150646FRALLMD6
113	457150646FRALLMD6
114	457150646FRALLMD6
115	457150646FRALLMD6
116	457150646FRALLMD6
122	457150646FRALLMD6
123	457150646FRALLMD6
125	457150646FRALLMD6
130	457150646FRALLMD6
131	457150646FRMEPLEZ
132	457150646FRMEPLEZ
134	457150646FRALLMD6
136	457150646FRALLMD6
137	457150646FRALLMD6
138	457150646FRALLMD6
139	457150646FRALLMD6



Model List

Model Number	Basic UDI-DI
140	457150646FRPLMEG2
141	457150646FRPLMEG2
142	457150646FRPLMEG2
145	457150646FRALLMD6
152	457150646FRALLMD6
181	457150646FRPLMEG2
182	457150646FRPLMEG2
183	457150646FRPLMEG2
225	457150646FRALLMD6
226	457150646FRALLMD6
800	457150646HRMEPLFT
900L	457150646FRALLMD6
901	457150646FRALLMD6
901L	457150646FRALLMD6
1000	457150646FRALLMD6
1110	457150646FRALLMD6
1111	457150646FRALLMD6
1112	457150646FRALLMD6
1113	457150646FRALLMD6
1221	457150646FRALLMD6
1231	457150646FRALLMD6
1232	457150646FRALLMD6
1233	457150646FRALLMD6
1234	457150646FRALLMD6
1235	457150646FRALLMD6
1300	457150646FRALLMD6
1301	457150646FRALLMD6
3001	457150646FRALLMD6
3002	457150646FRALLMD6
3003	457150646FRALLMD6

