



# DECLARATION of CONFORMITY

## ALGINATES

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## *EU DECLARATION OF CONFORMITY*

### *According to Annex IV of UE Regulation 2017/745*

|                                  |                                          |
|----------------------------------|------------------------------------------|
| Manufacturer                     | MAJOR PRODOTTI DENTARI S.P.A             |
| Address                          | Via Luigi Einaudi 23, I-10024 MONCALIERI |
| Single Registration Number (SRN) | IT-MF-000024700                          |

*The manufacturer declares on its own responsibility that the medical device:*

| Basic UDI-DI      | 8056640ALGE9                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-------------|-------|---------------------|-------|----------------------|-------|-------------------|-------|--------------------|-------|-------------------------|-------|--------------------------|-------|-------------------|-------|--------------------|-------|-----------------------------|-------|------------------------------|-------|--------------------|-------|---------------------|-------|----------------------------------|-------|-----------------------------------|-------|--------------------------------|-------|---------------------------------|
| Description       | <b>ALGINATES FOR DENTAL IMPRESSIONS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| Trade name, model | <table><thead><tr><th>CODE</th><th>DESCRIPTION</th></tr></thead><tbody><tr><td>A1000</td><td>ALGINMAJOR - 1x453G</td></tr><tr><td>A1024</td><td>ALGINMAJOR - 24X453G</td></tr><tr><td>A2000</td><td>ALGINMAX - 1X453G</td></tr><tr><td>A2024</td><td>ALGINMAX - 24X453G</td></tr><tr><td>A2100</td><td>ALGINMAX FRUIT - 1X453G</td></tr><tr><td>A2124</td><td>ALGINMAX FRUIT - 24X453G</td></tr><tr><td>A3000</td><td>ALGINKID - 1X453G</td></tr><tr><td>A3024</td><td>ALGINKID - 24X453G</td></tr><tr><td>A5000</td><td>ALGINPLUS TROPICAL - 1X453G</td></tr><tr><td>A5024</td><td>ALGINPLUS TROPICAL - 24X453G</td></tr><tr><td>A6000</td><td>ALGINPLUS - 1X453G</td></tr><tr><td>A6024</td><td>ALGINPLUS - 24X453G</td></tr><tr><td>A7000</td><td>ALGENIUX NORMAL SETTING - 1x453G</td></tr><tr><td>A7024</td><td>ALGENIUX NORMAL SETTING - 24x453G</td></tr><tr><td>A7100</td><td>ALGENIUX FAST SETTING - 1x453G</td></tr><tr><td>A7124</td><td>ALGENIUX FAST SETTING - 24x453G</td></tr></tbody></table> | CODE | DESCRIPTION | A1000 | ALGINMAJOR - 1x453G | A1024 | ALGINMAJOR - 24X453G | A2000 | ALGINMAX - 1X453G | A2024 | ALGINMAX - 24X453G | A2100 | ALGINMAX FRUIT - 1X453G | A2124 | ALGINMAX FRUIT - 24X453G | A3000 | ALGINKID - 1X453G | A3024 | ALGINKID - 24X453G | A5000 | ALGINPLUS TROPICAL - 1X453G | A5024 | ALGINPLUS TROPICAL - 24X453G | A6000 | ALGINPLUS - 1X453G | A6024 | ALGINPLUS - 24X453G | A7000 | ALGENIUX NORMAL SETTING - 1x453G | A7024 | ALGENIUX NORMAL SETTING - 24x453G | A7100 | ALGENIUX FAST SETTING - 1x453G | A7124 | ALGENIUX FAST SETTING - 24x453G |
| CODE              | DESCRIPTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A1000             | ALGINMAJOR - 1x453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A1024             | ALGINMAJOR - 24X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A2000             | ALGINMAX - 1X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A2024             | ALGINMAX - 24X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A2100             | ALGINMAX FRUIT - 1X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A2124             | ALGINMAX FRUIT - 24X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A3000             | ALGINKID - 1X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A3024             | ALGINKID - 24X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A5000             | ALGINPLUS TROPICAL - 1X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A5024             | ALGINPLUS TROPICAL - 24X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A6000             | ALGINPLUS - 1X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A6024             | ALGINPLUS - 24X453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A7000             | ALGENIUX NORMAL SETTING - 1x453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A7024             | ALGENIUX NORMAL SETTING - 24x453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A7100             | ALGENIUX FAST SETTING - 1x453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| A7124             | ALGENIUX FAST SETTING - 24x453G                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |
| Class             | I                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |      |             |       |                     |       |                      |       |                   |       |                    |       |                         |       |                          |       |                   |       |                    |       |                             |       |                              |       |                    |       |                     |       |                                  |       |                                   |       |                                |       |                                 |

It complies with EU Regulation 2017/745

|                   |                                                                                      |
|-------------------|--------------------------------------------------------------------------------------|
| Place, date       | MONCALIERI, 2024.02.22                                                               |
| Name and function | MONICA RENALDO, <i>Presidente</i>                                                    |
| Signature         |  |