

## Evaluation Claim skin tolerable / skin friendly Bewertung Claim hautverträglich / hautfreundlich

Application in the context of the intended purpose.

Anwendung im Rahmen der Zweckbestimmung.

### 1. Medical device / Product Group Medizinprodukt / Produktgruppe

| Product / -group<br>Produkt / - gruppe | REF   | Classification/Rule<br>acc MDR<br>Klassifizierung / Regel<br>gemäß MDR          | Intended Purpose<br>Zweckbestimmung                                                                                               |
|----------------------------------------|-------|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Mollelast el Fb 6/4                    | 34511 | Class: I /Is<br>Rule: 1<br>GMDN: 58964<br>UMDNS: 10-274<br>MD Code: 1214 / 1005 | Fixation Bandages are intended to be used for retention, for immobilization and for lymphological compression of fingers and toes |
| Mollelast el Fb 8/4                    | 34512 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 10/4                   | 34513 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 4/4 ep                 | 34514 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 6/4 ep                 | 34515 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 8/4 ep                 | 34516 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 10/4 ep                | 34517 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 4/4 ep                 | 14410 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 6/4 ep                 | 14411 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 8/4 ep                 | 14412 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 10/4 ep                | 14413 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 12/4 ep                | 14414 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 4/4                    | 19410 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 6/4                    | 19411 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 8/4                    | 19412 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 10/4                   | 19413 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 12/4                   | 19414 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 6/4 100 Stk            | 19427 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 8/4 100 Stk            | 19428 |                                                                                 |                                                                                                                                   |
| Mollelast el Fb 10/4 100 Stk           | 19429 |                                                                                 |                                                                                                                                   |
| Mollelast El Fb 6/4 ep 20Stk ste       | 20290 |                                                                                 |                                                                                                                                   |
| Mollelast El Fb 8/4 ep 20Stk ste       | 20291 |                                                                                 |                                                                                                                                   |
| Mollelast El Fb 10/4 ep 20Stk ste      | 20292 |                                                                                 |                                                                                                                                   |
| Mollelast El Fb 12/4 ep 20Stk ste      | 20293 |                                                                                 |                                                                                                                                   |

|                                   |         |  |  |
|-----------------------------------|---------|--|--|
| FIXELAST el Fb 8/10 ws*           | 109589  |  |  |
| FIXELAST el Fb 6/10 ws*           | 109590  |  |  |
| FIXELAST el Fb 4/10 ws*           | 109591  |  |  |
| FIXELAST el Fb 6/4 lose/20*       | 109592  |  |  |
| FIXELAST el Fb 8/4 lose/20*       | 109593  |  |  |
| FIXELAST el Fb 10/4 lose/20*      | 109594  |  |  |
| FIXELAST el Fb 4/4 lose/20*       | 109595  |  |  |
| Mollelast 4cmX4m lose 520 Stk/TC  | 2015459 |  |  |
| Mollelast 6cmX4m lose 990 Stk/TC  | 2015458 |  |  |
| Mollelast 8cmX4m lose 750 Stk/TC  | 2014821 |  |  |
| Mollelast 10cmX4m lose 550 Stk/TC | 2015457 |  |  |
| Mollelast 12cmX4m lose 100 Stk/TC | 2014820 |  |  |

## 2. Biocompatibility Biokompatibilität

Evaluation based on: BRA-30-00224-01 – BRA 30-00222-01 and  
Add 01 to BRA-30-00224-01 – BRA 30-00222-01

*Bewertung basiert auf*

Based on the referenced document, is there a positive assessment regarding the biological endpoints Irritation, Cytotoxicity, Sensitization available?

*Basierend auf dem referenzierten Dokument, ist eine positive Bewertung der biologischen Endpunkte Irritation, Zytotoxizität, Sensibilisierung verfügbar?*

☒ Yes / Ja ☐ No / Nein

If yes, insert the summary of the biological risk assessment here:

*Wenn Ja, bitte die Zusammenfassung der Biologischen Risikobewertung hier einfügen:*

*In conclusion, the device safety is considered adequate.*

*"The risk assessment undertaken indicates that, regarding the intended application and use of the devices, the overall residual biological risks posed by Mollelast / Fixelast associated with the identified hazards are acceptable." BRA-30-00224-01 – BRA 30-00222-01*



### 3. Risk Analysis Risikoanalyse

Risk Management File Risikomanagementakte: RMF 30-00282-FN-001 Number of Risk Analysis Nummer der Risikoanalyse:

RA 30-00282-00

Period under review, Zeitperiode: 01.01.2012 – 31.12.2019

Risk evaluation matrix, Risikobewertungsmatrix:

Severity

| Probability  | Minor 1 | Moderate 2                                  | Serious 3 | Critical 4 | Catastrophic 5 |
|--------------|---------|---------------------------------------------|-----------|------------|----------------|
| Frequent 5   |         |                                             |           |            |                |
| Probable 4   |         |                                             |           |            |                |
| Occasional 3 |         |                                             |           |            |                |
| Remote 2     |         |                                             |           |            |                |
| Improbable 1 |         | Skin irritation /<br>allergy:<br>< 0.0001 % |           |            |                |

| Fulfilled (in the green area)<br>Erfüllt (im grünen Bereich) | Yes<br>Ja | No<br>Nein | Notices<br>Anmerkungen |
|--------------------------------------------------------------|-----------|------------|------------------------|
| In the green area<br>Im grünen Bereich                       | Yes       |            |                        |
| In the yellow area<br>Im gelben Bereich                      |           |            |                        |
| In the red area<br>Im roten Bereich                          |           | No         |                        |

#### 4. Release Unterschriften

The claim skin-friendly / skin tolerable is evaluated as:

Der Claim hautfreundlich / hautverträglich wird bewertet als:

☒ Accepted / Akzeptiert      ☐ Rejected / Abgelehnt

This document has to be updated if the biological risk assessment and/or the risk analysis is changed. The GMK Manager is responsible to issue the update process.

*Dieses Dokument muss bei Änderung der biologischen Risikobewertung und/oder Risikoanalyse geändert werden. Der GMK Manager ist für das starten des Update Prozess verantwortlich.*

|                                    | Name            | Date<br>Datum | Signature<br>Unterschrift                                                             |
|------------------------------------|-----------------|---------------|---------------------------------------------------------------------------------------|
| GMK Manager<br>GMK Manager         | Wanna Binder    | 2020-03-30    |  |
| Risk Manager<br>Risikomanager      | Syed Bari       | 2020-03-30    |  |
| Vigilance Officer<br>International | Dr. Martin Abel | 2020-03-30    |  |