

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Kinesiology Tape Red**

Item No.: 10110

Basic-UDI-DI (GMN): 426031010110Z6

UDI-DI (GTIN): 0609465805160

Product picture:



Intended use: For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH

Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuninge, Germany hereby declares that following product:

Product: **Kintex Kinesiology Tape Black**

Item No.: 10120

Basic-UDI-DI (GMN): 426031010120Z9

UDI-DI (GTIN): 0609613625749

Product picture:



Intended use: For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for i- vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Kinesiology Tape Blue**

Item No.: 10130

Basic-UDI-DI (GMN): 426031010130ZC

UDI-DI (GTIN): 0609613625718

Product picture:



Intended use: For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH

Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Kinesiology Tape Green**

Item No.: 10140

Basic-UDI-DI (GMN): 426031010140ZF

UDI-DI (GTIN): 0609613625725

Product picture:



Intended use: For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

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Andreas Jetter, CEO Apaloo GmbH

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The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Kinesiology Tape Pink**

Item No.: 10150

Basic-UDI-DI (GMN): 426031010150ZJ

UDI-DI (GTIN): 0609613625732

Product picture:



Intended use: For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

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The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Kinesiology Tape Beige**

Item No.: 10160

Basic-UDI-DI (GMN): 426031010160ZM

UDI-DI (GTIN): 0609613625756

Product picture:



Intended use: For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH

Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date

Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

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(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Kinesiology Tape Yellow**
 Item No.: 10170
 Basic-UDI-DI (GMN): 426031010170ZQ
 UDI-DI (GTIN): 4260310410586
 Product picture:



Intended use: For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date

Andreas Jetter, CEO Apaloo GmbH

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(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product:	Kintex Kinesiology Tape Darkblue
Item No.:	10180
Basic-UDI-DI (GMN):	426031010180ZT
UDI-DI (GTIN):	4260310410579
Product picture:	
Intended use:	For use as pain, muscle, lymph and correction tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name:	Apaloo GmbH
Address:	Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

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(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Mix Box**
 Item No.: 20900
 Basic-UDI-DI (GMN): 4260310209002R
 UDI-DI (GTIN): 0609613625831

Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


 Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

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The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Beige A**
 Item No.: 20911
 Basic-UDI-DI (GMN): 2460310209112W
 UDI-DI (GTIN): 0609613625763
 Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


 Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Pink A**
 Item No.: 20912
 Basic-UDI-DI (GMN): 4260310209122Y
 UDI-DI (GTIN): 0609613625787
 Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date

Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Blue A**
 Item No.: 20913
 Basic-UDI-DI (GMN): 42603102091332
 UDI-DI (GTIN): 0609613625770
 Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, den 30.04.2021

Place/Date

Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Beige B**
 Item No.: 20921
 Basic-UDI-DI (GMN): 4260310209212Z
 UDI-DI (GTIN): 0609613625848
 Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


 Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Pink B**
 Item No.: 20922
 Basic-UDI-DI (GMN): 42603102092233
 UDI-DI (GTIN): 0609613626081
 Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


 Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Blue B**
 Item No.: 20923
 Basic-UDI-DI (GMN): 42603102092335
 UDI-DI (GTIN): 0609613625817
 Product picture: 

Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


 Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product:	Kintex Cross Tape Beige C
Item No.:	20931
Basic-UDI-DI (GMN):	42603102093134
UDI-DI (GTIN):	0609613626074
Product picture:	
Intended use:	For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Pink C**
 Item No.: 20932
 Basic-UDI-DI (GMN): 42603102093236
 UDI-DI (GTIN): 0609613625824
 Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


 Andreas Jetter, CEO Apaloo GmbH

EU-Declaration of Conformity

according to the MDR 2017/745/EU, Annex IV

The production of the product complies with Class I according Annex VIII

(Nomenclature term: 10-028 hypoallergenic adhesive plaster)

Apaloo GmbH, Staigstr. 9, 78609 Tuningen, Germany hereby declares that following product:

Product: **Kintex Cross Tape Blue C**
 Item No.: 20933
 Basic-UDI-DI (GMN): 42603102093338
 UDI-DI (GTIN): 4260310410012
 Product picture:



Intended use: For use as pain, muscle and lymph tape

meets all the requirements of the following regulation which are applicable:

MDR Regulation (EU) 2017/745, Annex IV

The above mentioned conformity assessment procedure has been followed and all provisions of the Regulation and the following relevant harmonised standards are complied with:

Section	Title
ISO13485:2016	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Symbols for labelling on medical devices
ISO 14971	Risk management on medical devices

A complete technical documentation with risk analysis is available. The instructions for use belonging to the product are available in the national language of the user.

This declaration becomes the responsibility of the manufacturer:

Name: Apaloo GmbH
 Address: Staigstr. 9, 78609 Tuningen, Germany

The manufacturer bears sole responsibility for issuing this declaration of conformity in respect of compliance with the essential requirements and for drawing up the technical documentation.

The above mentioned product is a medical device according to Article 2 (1) of the Regulation. It meets the essential safety and performance requirements set out in Annex I of the Regulation.

This declaration includes the LOT numbers 210101 – 261231 and is valid until 31.12.2026.

Tuningen, 30.04.2021

Place/Date


 Andreas Jetter, CEO Apaloo GmbH