



DECLARATION CE DE CONFORMITE / EC DECLARATION OF CONFORMITY

LCH Medical Products, 12-14 rue Sarah Bernhardt – 92600 Asnières-sur-Seine – FRANCE,

assurons et déclarons sous notre seule responsabilité que le dispositif médical /
certify and declare under our sole responsibility that the medical device :

- **SETS DE SOINS DE PANSEMENT ET INSTRUMENTS stériles à usage unique,**
Voir la liste des produits LCH associée à cette déclaration en annexe
- ***Sterile disposable WOUND CARE KITS AND INSTRUMENTS***
See List of applicable LCH products related to this declaration

Répond aux exigences essentielles et aux recommandations de la Directive Européenne 93/42/CEE amendée par la Directive 2007/47/CEE et qu'il est en conformité avec l'arrêté du 15 mars 2010 relatif aux dispositifs médicaux /

Is in conformity with the essential requirements and with the recommendations of the Directive 93/42/EC amended by Directive 2007/47/EC and is compliant with the French order of March 15th, 2010 related to medical devices

Les dispositifs médicaux appartiennent à classe Is suivant les règles 1 et 4.
(voir annexe)

Medical device of class Is according to the rules 1 and 4 (see annex)

Cette déclaration est faite sur la base du Certificat N° ECM20MDD17 relatif au marquage CE selon la Directive Européenne 93/42/CEE, Annexe V établi par Ente Certificazione Macchine (ECM) s.r.l Via ca' Bella, 243/A – 40053 Valsamoggia (BO) – Italia, Organisme notifié N°1282.

This declaration is based on EC Certificate N° ECM20MDD17 related to EC marking according the European Directive 93/42/EC, Annex V issued by Ente Certificazione Macchine (ECM) s.r.l Via ca' Bella, 243/A – 40053 Valsamoggia (BO) – Italia, Notified body N°1282

Lieu et date d'émission / *Place and date of issue*

Asnières-sur-Seine, 02/12/2020

Par/by Emmanuelle GARNIER

Directeur Qualité et Affaires Réglementaires / *Quality and Regulatory Affairs Manager*



Annexe de la déclaration CE de conformité de la gamme de dispositifs médicaux /
Annex of the EC declaration of conformity for the range of medical devices
Sets de soins de pansement et instruments stériles à usage unique / *Sterile*
disposable wound care kits and instruments

| REFERENCE LCH | Désignation | Règle |
|------------------|---|-------|
| DK-40858 | Set de pansements/ Dressing Kit | 4 |
| DK-40859 | Set de pansements/ Dressing Kit | 4 |
| DK-40860 | Set de pansements/ Dressing Kit | 4 |
| DK-40861 | Set de pansements/ Dressing Kit | 4 |
| DK-801 | Set de pansements/ Dressing Kit | 4 |
| DK806 | Set de pansement/ Dressing Kit | 4 |
| DK-808E | Set de pansement/ Dressing Kit | 4 |
| DK-809C | Set de pansement/ Dressing Kit | 4 |
| DK819 | Set de pansement/ Dressing Kit | 4 |
| DK823 | Set de pansement/ Dressing Kit | 4 |
| DK830 | Set de pansement/ Dressing Kit | 4 |
| DK-837C | Set de pansement/ Dressing Kit | 4 |
| DK-854 | Set de pansement/ Dressing Kit | 4 |
| DK872 | Set de pansement/ Dressing Kit | 4 |
| DK-874 | Set de pansement/ Dressing Kit | 4 |
| DK-901C | Set de pansement/ Dressing Kit | 4 |
| DK902 | Set de pansement/ Dressing Kit | 4 |
| DK-903 | Set de pansement/ Dressing Kit | 4 |
| PBS-8200B | Pince anatomique/ Anatomical forcep | 1 |
| PBS-8300G | Pince anatomique/ Anatomical forcep | 1 |
| PBS-8349 | Pince kocher/ Kocher forcep | 1 |
| SA-300D | Set de pansement/ Dressing Kit | 4 |
| SCI-01 | Ciseaux bouts pointus/ Sharp scissors | 1 |
| SCI-02 | Ciseaux bouts ronds/ Blunt scissors | 1 |
| SCI-03 | Ciseaux bouts mousses et pointu/ Sharp and blunt scissors | 1 |

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Novomed Group n° SRN FR-MF-000022240 : situé au 12-14 rue Sarah Bernhardt – 92600 Asnières-sur-Seine – FRANCE,
Assurons et déclarons sous notre seule responsabilité que les dispositifs médicaux / *Certify and declare under our sole responsibility that the medical devices :*

Famille de produit/ *Product family :*

Sets et instruments stériles pour la pose de suture, la préhension de tissu et couper la peau / *Sterile kits and instruments for suture delivery, tissue clamping and cut skin*

| Reference SAP | Reference SAGE | Brand Name | Designation | Destination |
|---------------|----------------|------------|---|----------------------------------|
| 77904 | DK906 | LCH | Set de micro chirurgie/ Micro surgery kit | Pose de suture / Suture delivery |
| 8015 | DK924/CTN | | Set de pose de sutures/ Wound closure kit | Pose de suture / Suture delivery |
| 77905 | DK926 | | Set de suture/ Wound closure kit | Pose de suture / Suture delivery |
| 77906 | DK926/CTN | | Set de suture/ Wound closure kit | Pose de suture / Suture delivery |
| 27291 | DK928 | | Plateau pour Biopsie Dermato/ Face and hand surgery-biopsy | Pose de suture / Suture delivery |
| 79877 | DK930 | | Plateau pour Biopsie Dermato/ Face and hand surgery-biopsy | Pose de suture / Suture delivery |
| 40862 | DK-9-40862 | | Set de suture/ Wound closure kit | Pose de suture / Suture delivery |
| 40865 | DK-9-40865 | | Set de pose suture/Suture delivery kit | Pose de suture / Suture delivery |
| 75601 | MTS-03101 | | Ciseaux chirurgicaux / Operating scissors | Couper la peau / Cut skin |
| 79409 | MTS-03110 | | Ciseaux chirurgicaux / Operating scissors | Couper la peau / Cut skin |
| 75600 | MTS-03121 | | Ciseaux chirurgicaux / Operating scissors | Couper la peau / Cut skin |
| 79410 | MTS-03131 | | Ciseaux chirurgicaux / Operating scissors | Couper la peau / Cut skin |
| 79411 | MTS-03132 | | Ciseaux chirurgicaux / Operating scissors | Couper la peau / Cut skin |
| 75700 | MTS-03141 | | Ciseaux /Scissors | Couper la peau / Cut skin |
| 75300 | MTS-03142 | | Ciseaux /Scissors | Couper la peau / Cut skin |
| 79412 | MTS-03143 | | Ciseaux /Scissors | Couper la peau / Cut skin |
| 79413 | MTS-03151 | | Ciseaux /Scissors | Couper la peau / Cut skin |
| 75500 | MTS-03202 | | Ciseaux à dissection Mayo/ Mayo Dissecting Scissors | Couper la peau / Cut skin |
| 44694 | MTS-03203 | | Ciseaux à dissection Mayo/ Mayo Dissecting Scissors | Couper la peau / Cut skin |
| 44485 | MTS-03204 | | Ciseaux à dissection Mayo/ Mayo Dissecting Scissors | Couper la peau / Cut skin |
| 74902 | MTS-03330 | | Ciseaux à dissection Metzenbaum/ Metzenbaum Dissecting Scissors | Couper la peau / Cut skin |
| 74901 | MTS-03331 | | Ciseaux à dissection Metzenbaum/ Metzenbaum Dissecting Scissors | Couper la peau / Cut skin |
| 74900 | MTS-03332 | | Ciseaux à dissection Metzenbaum/ Metzenbaum Dissecting Scissors | Couper la peau / Cut skin |
| 75802 | MTS-03501 | | Ciseaux iridectomie / Iridectomy scissors | Couper la peau / Cut skin |

| | | | | |
|-------|-----------|--|--|------------------------------------|
| 44695 | MTS-03511 | | Ciseaux iridectomie / Iridectomy scissors | Couper la peau / Cut skin |
| 75800 | MTS-03521 | | Ciseaux iridectomie / Iridectomy scissors | Couper la peau / Cut skin |
| 75801 | MTS-03531 | | Ciseaux iridectomie / Iridectomy scissors | Couper la peau / Cut skin |
| 76403 | MTS-05001 | | Pince à Dissection Fine/Thin Dissecting forcep | Prehension tissu / Tissue clamping |
| 76404 | MTS-05002 | | Pince à Dissection Fine/Thin Dissecting forcep | Prehension tissu / Tissue clamping |
| 76405 | MTS-05003 | | Pince à Dissection Fine/Thin Dissecting forcep | Prehension tissu / Tissue clamping |
| 76400 | MTS-05020 | | Pince à Dissection Fine/Thin Dissecting forcep | Prehension tissu / Tissue clamping |
| 76401 | MTS-05021 | | Pince à Dissection Fine/Thin Dissecting forcep | Prehension tissu / Tissue clamping |
| 76402 | MTS-05022 | | Pince à Dissection Fine/Thin Dissecting forcep | Prehension tissu / Tissue clamping |
| 75001 | MTS-05700 | | Pince Micro Adson/Adson micro forcep | Prehension tissu / Tissue clamping |
| 75002 | MTS-05701 | | Pince Micro Adson/Adson micro forcep | Prehension tissu / Tissue clamping |
| 75000 | MTS-05702 | | Pince Micro Adson/Adson micro forcep | Prehension tissu / Tissue clamping |
| 44698 | MTS-090 | | Porte-aiguille/Needle holder | Pose de suture / Suture delivery |
| 46468 | 21.080 | | Ciseaux chirurgicaux droits pointus / Straight and sharpened Operating scissor | Couper la peau / Cut skin |
| 46469 | 21.081 | | Ciseaux chirurgicaux courbés pointus / Straight and curved Operating scissor | Couper la peau / Cut skin |
| 46471 | 21.083 | | Ciseaux chirurgicaux courbés mousse / Curved and stretch Operating scissor | Couper la peau / Cut skin |
| 47141 | 21.091 | | Pince à dissection micro adson sans griffe / Micro Adson/Adson dissecting forcep without tooth | Prehension tissu/ Tissue clamping |
| 46472 | 21.095 | | Pince à dissection ultrafine adson avec griffe/ Ultra thin dissecting adson forcep with tooth | Prehension tissu/ Tissue clamping |
| 46473 | 21.096 | | Pince à dissection ultrafine adson avec griffe/ Ultra thin dissecting adson forcep without tooth | Prehension tissu/ Tissue clamping |
| 47308 | 21.100 | | Porte Aiguille Micro Halsey / Micro Halsey Type Needle Holder | Pose de suture / Suture delivery |
| 47403 | 21.101 | | Porte-aiguille Micro Halsey / Micro Halsey Type Needle holder | Pose de suture / Suture delivery |
| 46475 | 21.140 | | Crochet de Gillies/ Gillies Hook | Prehension tissu/ Tissue clamping |
| 46478 | 21.160 | | Ciseaux à dissection STEVENS courbes/ Stevens thin curved scissors | Couper la peau / Cut skin |
| 46479 | 21.161 | | Ciseaux à dissection STEVENS droits/ Stevens thin straight scissors | Couper la peau / Cut skin |
| 47434 | 31.316 | | Set de Suture Precisio 1' / Kit For Suture Precisio 1' | Pose de suture / Suture delivery |
| 46486 | 31.403 | | Set de Suture "Precision" / Kit For Suture "Precision" | Pose de suture / Suture delivery |
| 46480 | 31.303 | | Set de Suture "Precision" / Kit For Suture "Precision" | Pose de suture / Suture delivery |

Répondent aux exigences essentielles et aux recommandations de la Directive Européenne 93/42/CEE amendée par la Directive 2007/47/CEE et qu'ils sont en conformité avec l'arrêté du 15 mars 2010 relatif aux dispositifs médicaux /

Are in conformity with the essential requirements and with the recommendations of the Directive 93/42/EC amended by Directive 2007/47/EC and are compliant with the order of March 15th, 2010 related to medical devices

Les dispositifs médicaux sont de la classe IIa selon la règle 6 conformément à l'annexe IX de la directive / *Medical devices are class IIa according to the 6 rule in accordance with Annex IX of the Directive.*

Organisme Notifié/*notified body*: GMED.

Numéro/*Number*: n°0459

Certificate CE / *EC certificate N°* : n° 36979 & n° 36980

Voie de conformité/*Route of conformity*: Annex V

Lieu et date d'émission / *Place and date of issue*

Asnières-sur-Seine, 26/06/2023

Par/*by* Marie CARRIERE

Personne chargée de veiller au respect de la Réglementation (PCVRR) / *Person responsible for regulatory compliance (PRRC)*

PCVRR/PRRC
