Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0772 QS/NB/a

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the product – medical device of Class IIa

Heating system under/overlay, electric, home use
model: **NM-80**, trade name: **NUGABEST**

manufactured by company

NUGA MEDICAL Co., Ltd.
San 2-1, Gagok-ri, Jijeong-myeon, Wonju-si, Gangwon-do, KOREA

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601230/2011 and No. 803601670/2012, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the* ***15th September 2016*** *at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 20th August 2012

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Replaces the withdrawn EC Certificate No. 11 0772 QS/NB issued on 16th September 2011

Certificate – Сертификат – 證明書 – Certificat – 인증서 – شهادة

Certificate of Compliance

No. 1S160108.NM0044

Certificate's Holder:	NUGA MEDICAL Co., Ltd. 185, Jiraeut-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Korea
Certification ECM Mark:	Type Approved
Product:	Thermal Massager
Model(s):	NM-80
Verification to:	Standard: EN 60335-1:2012, EN 60335-2-32:2008, EN 55014-1:2011(A2), EN 55214-2:2006 (A2), EN 61000-3-2:2009(A2), EN 61000-3-3:2008 related to CE Directive(s): 2014/35/EU (Low Voltage) 2014/30/EU (Electromagnetic Compatibility)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.entecerma.it.
Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.
The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Certification ECM Mark.
This certificate can be checked for validity at www.entecerma.it

Date of issue 08 January 2016

Chief Manager
Tim Manca

Expiry date 07 January 2021

Deputy Manager
Viola Miller

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) – ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌍 www.entecerma.it

Certificate – Сертификат – 證明書 – Certificat – 인증서 – شهادة

Certificate of Compliance

No. 15160108.NM0045

Certificate's Holder:	NUGA MEDICAL Co., Ltd. 185, Jiraeul-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Korea
Certification ECM Mark:	Type Approved
Product:	Thermal Massager
Model(s):	NM-90
Verification to:	Standard: EN 60335-1:2012, EN 60335-2-32:2008, EN 55014-1:2011(A2), EN 55214-2:2008(A2), EN 61000-3-2:2009(A2), EN 61000-3-3:2008 related to CE Directive(s): 2014/35/EU (Low Voltage) 2014/30/EU (Electromagnetic Compatibility)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.enteceima.it.
Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.
The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Certification ECM Mark.
This certificate can be checked for validity at www.enteceima.it

Date of issue 08 January 2016

Chief Manager
Tim Mahon

Expiry date 07 January 2021

Deputy Manager
Viola Miller

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@enteceima.it 🌐 www.enteceima.it

Product Certification Body
INSTITUTE FOR TESTING AND CERTIFICATION Plc
Tomas Bata Ave 299, Louky, 763 02 Zlin, CZECH REPUBLIC

TYPE CERTIFICATE OF CONFORMITY

No 10 0383 T/ITC/b

Product: **THERMAL MASSAGER, Model: NM-200**

Manufacturer: **NUGA MEDICAL CO., LTD.**

San 2-1, Gagok-ri, Jijeong-myeon, Wonju-si, Gangwon-do, KOREA

The Product Certification Body has assessed **the Product** and resolved that it **fully complies with the applicable essential requirements of European Directives No 2006/95/EC on electrical safety and No 2004/108/EC on electromagnetic compatibility,** as amended, which have been implemented into the following harmonized European standards:

EN 60335-1	*Safety of household and similar electrical appliances – Part 1: General requirements*
EN 60335-2-32	*Household and similar electrical appliances – Safety. Part 2-32: Particular requirements for massage appliances*
EN 55014-1	*EMC requirements for household appliances, electric tools and similar apparatus – Part 1: Emissions*
EN 55014-2	*EMC requirements for household appliances, electric tools and similar apparatus – Part 2: Product family standard*
EN 61000-3-3	*EMC. Part 3-3: Limitation of voltage changes, fluctuations and flicker*

The product description, documents, assessment procedures, and evaluations of the examination are presented in the Final Reports No 3130 00115/2010, 3130 00145/2012, and 3130 00158/2013, that are enclosed to this certificate.

This Certificate has been issued under the following conditions:

1. *It applies only to the above referenced models of the Product.*
2. *It does not imply that the Certification Body has performed any surveillance or control of its manufacture.*
3. *The Manufacturer shall assure that all products of the respective models conform to the certified type.*
4. *The Certificate remains valid until the manufacturing conditions, relevant harmonized standards or relevant legislation are changed, but until the date of expiration at the latest.*
5. *After fulfilling the relevant EU legislation requirements, the Manufacturer shall issue a Declaration of Conformity and affix CE marking according to Regulation (EC) 765/2008 (Chapter IV and Annex II) to each Product of the above referenced models.*
6. *Since January 2013, the Declaration of Conformity shall also include the conformity with Directive No 2011/65/EU on restriction of hazardous substances.*

Date of issue: **2013-06-01**

Date of expiration: **2016-06-30**

Mr Pavel VANEK
Head of the Certification Body

Release: 1305

Validity of this Certificate can be verified at: www.itczlin.cz/cert-en.php

Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0774 QS/NB/a

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the product – medical device of Class IIa

Heating system under/overlay, electric, home use
model: **NM-2500**, trade name: **NUGABEST**

manufactured by company

NUGA MEDICAL Co., Ltd.
San 2-1, Gagok-ri, Jijeong-myeon, Wonju-si, Gangwon-do, KOREA

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601230/2011 and No. 803601670/2012, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **15th September 2016** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlin, on 20th August 2012

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Replaces the withdrawn EC Certificate No. 11 0774 QS/NB issued on 16th September 2011

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Conformity

No. EC.1282.15141126.NMQC73

Certificate's Holder: NUGA MEDICAL CO., LTD.
185, Jiraeul-ro (San 2-1, Gagok-RI), Jijeong-myeon, Wonju-si, Gangwon-do, Korea

Certification Mark: CE ® Type Approved

Product: Thermal Massager

Model(s): NM-2500

Verification to: Standard:
EN 60335-1:2012,
EN 60335-2-32:2003+A1:2008,
EN 62233:2008,
EN 55014-1:2006+A2:2011,
EN 55014-2:1997+A2:2008 (Category II),
EN 61000-3-2:2006+A1:2009+A2:2009,
EN 61000-3-3:2008

related to Directive(s):
2006/95/EC (Low Voltage)
2004/108/EC (Electromagnetic Compatibility)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Safety Compliance Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use.
Other relevant Standards and/or Directives have to be observed in case they are applicable.
Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.
The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Safety Compliance Mark.
This certificate can be checked for validity at **www.entecerma.org**

Date of issue 26 November 2014

Chief Manager
Tim Mahon

Expiry Date 25 November 2019

Deputy Manager
Viola Miller

Ente Certificazione Macchine Srl
Via Co[illegible] 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 12 0786 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the product – medical device of Class IIa:

Combinational Stimulator
model: NM-5000

manufactured by company

Nuga Medical Co., Ltd.
San 2-1, Gagok-ri, Jijeong-myeon, Wonju-si, Gangwon-do, Korea

are manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2., of the Directive 93/42/EEC.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3, and 4, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601597/2012, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **25th September 2017** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlin, on 26th September, 2012

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Management Systems Certification Body No. 3002
Institute for Testing and Certification, Inc.
třída Tomáše Bati 299, 764 21 Zlín, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 13 0282 SJ

We confirm on the basis of a performed audit that company

NUGA MEDICAL CO., LTD.

San 2-1, Gagok-ri, Jijeong-myeon, Wonju-si, Gangwon-do, Korea
Company Reg. No.: 126-81-63382

has implemented and documented a functional quality management system in compliance with the requirements of the standard

EN ISO 13485:2012

Covering the following activities:

- Design and Development, Manufacturing, Service and Distribution for Combinational Stimulator, Computed Radiography Scanner, Heating System Under/Overlay, Electric, Home Use and Heating Pad System Under/Overlay, Electric, Home Use

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233403524/2013. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.

S 3002

Date of Issue: 06. 09. 2013
Valid until: 06. 09. 2016

Date of the first certification awarding: 20. 11. 2007

Ing. Pavel Vaněk
Head of Certification Body

行政院衛生署醫療器材許可證

衛署醫器輸字第 017028 號

簽審文件號碼：DHA00601702800

中文名稱：“麗可” 醫療用溫熱刺激器

英文名稱：“NUGA” Combinational Stimulator For Medical Use By Personal

類　　別：第 O 類：物理醫學科用裝置

規　　格：NM-5000
以下空白

藥商名稱：麗可醫療器股份有限公司

製造廠名稱：NUGA MEDICAL CO., LTD.

製造廠地址：73-1, Dae SsangRyung-Ri, ChoWol-Myeon, GwangJu-Si, Kyonggi-Do, Korea

效　　能：溫熱：改善局部血液循環，緩和肌肉之神經痛
低周波：減輕酸痛

處　　方：空白

前項醫療器材經本署審核與藥事法之規定相符准發給許可證以資證明

行政院衛生署署長

侯勝茂

發證日期　玖拾伍　年　捌　月　貳拾壹　日

有效日期　壹佰　年　捌　月　貳拾壹　日

核准展延至	105 年 8 月 21 日	110 年 8 月 2 日	年 月 日	年 月 日
文號	00505694105602085O			

F 008425 藥商名稱變更、中文品名變更 藥商名稱變更 藥商名稱變更 藥商名稱變更
(移轉) 標籤、仿單變更 英文品名變更 (許可證換發)

行政院衛生署第一等級醫療器材許可證

衛署醫器輸壹 字第 012208 號

簽審文件號碼：**DHA04401220807**

中文名稱：〝路加〞 動力式熱敷墊（未滅菌）

英文名稱：〝Nuga〞 Heating pad (Non-sterile)

類　　別：第 O 類：物理醫學科用裝置

規　　格：空白

藥商名稱：路加貝斯特醫療器股份有限公司

製造廠名稱：NUGA MEDICAL CO., LTD.

製造廠地址：DONGWHA MEDICAL INSTRUMENT COMPLEX,#1642-10 DONGWHA 3-RI, MUNMAK-EUP, WONJU-SI, GANGWON-DO, KOREA

效　　能：限醫療器材管理辦法「動力式熱敷墊(O.5740)」第一等級鑑別範圍。

處　　方：空白。

前項醫療器材經本署審核與藥事法之規定相符應發給許可證以資證明

行政院衛生署署長

邱文達

發證日期　壹佰零壹　年　玖　月　貳拾柒　日

有效日期　壹佰零陸　年　玖　月　貳拾柒　日

核准展延至	年 月 日	年 月 日	年 月 日	年 月 日
文號	10601294			

K 023249

藥商名稱變更(移轉) 藥商名稱變更


GREAT PLACE TO WORK
2011
우리지역 일하기 좋은 기업
(주)누가의료기
귀사는 지식경제부와 강원도가 공동으로
주최하는 '우리지역 일하기 좋은 기업'에
선정되었기에 이 패를 드립니다.
2011. 6. 3
지식경제부
강원도


IR 52 將英實賞
1994
韓国科學財團 · 科學技術處 · 韓国放送公社


HIT
인 증 패
부 문 : 의료기
회사명 : 누가의료기
제품명 : NM-5000
귀사의 제품이 일간스포츠에서
시행한 2010년도 상반기 히트상품
특집 상품에 선정되었기에
이 패를 드립니다.
2010년 7월 8일
IS 일간스포츠
대표이사 정경문


2010
HIT
한국일보선정
누가의료기
NM-5000
기업의 신상품개발 및 기술혁신
2010 상반기 히트상품에 귀사의 상품
선정되었기에 이 상을 드립니다.
2010년 7월 1일
한국일보
사장 이 종 승

第 94-02-01 號

賞 狀

所屬 : (株)韓國産業電子

姓名 : 曺 勝 鉉

위 사람은 每日經濟新聞社와 韓國産業技術振興協會가 공동주관하는 「IR 52 蔣英實賞」의 1994 년도 제 2 주 수상제품으로 선정된 체외 충격파 쇄석기 를 개발하여 産業技術革新에 기여한 공로가 크므로 이에 상장과 메달을 드립니다

1994年 1月 8日

科學技術處長官 金始中

제 171431 호

표 창 장

㈜누가의료기

위는 지역산업진흥을통하여국가산업발전에 이바지한 공로가 크므로 이에 표창합니다.

2009 년 7 월 1 일

대 통 령 이 명 박

이 증을 대통령표창부에 기재합니다.

행정안전부장관 이 달 곤


이천만대 수출의 탑

感　謝　牌

青島麗可醫療器械（有）
會長　　曹勝鉉

閣下及貴公司多年來在企業自身發展的同時，牽線搭橋，為眾多韓國企業瞭解青島、熱愛青島、立足青島做出了貢獻！謹以此牌表示感謝！

青島市人民政府
副市長　吳經建
二〇〇七年七月十九日


은
상


벤처천억기업


칠천도매 수해의 비


공 로 패
50
NUGA BEST
조 승 현 회장
조승현 회장님께서는 이화경영의 CEO겸임교수로 재직하시면서 글로벌 리더로서 해박한 지식과 경험을 후진들에게 전수하시고 여성경영인 양성에 힘쓰시는 등 이화경영의 발전에 기여하셨습니다.
이에 경영학과 창립 50주년을 맞이하여 그 공로를 높이 치하하고 감사하는 구성원 모두의 뜻을 담아 이 상패를 드립니다.
2014년 11월 12일
이화여자대학교 경영대학장 김 성 국


히트상품 인증패
온열치료기 부문
(주)누가의료기 | NM5000
위 상품은 우수한 품질과 뛰어난 마케팅으로
소비자들로부터 가장 인기있는 상품으로 인정받아
2010 상반기 히트상품으로 선정되었기에
인증패를 드립니다.
2010. 7. 14.
스포츠서울

Serial No. 2010-127-01

kotra

KOTRA SEAL OF EXCELLENCE

A Mark of Quality, High Technology and Trustworthiness

㈜누가의료기

귀 사는 우수한 품질과 높은 기술력으로 국가 수출 증대 및 경제 발전에 기여할 가능성이 크므로 2010년 KOTRA 보증브랜드 기업으로 선정함.

May 4, 2010

최 경 환

최 경 환 지식경제부 장관
Choi, Kyunghwan
Minister of Knowledge Economy

조 환 익

조 환 익 KOTRA 사장
Cho, Hwan-Eik
President and CEO
Korea Trade-Investment Promotion Agency