

QMS 適合性調査 確認書

Confirmation Letter for J-QMS Audit



調査対象 : Ortho Solutions Sdn Bhd
Audited Facility 10, Jalan IKS Juru Jaya, Taman IKS Juru Jaya, 14100 Simpang Ampat, Penang. Malaysia

調査実施日 : 2015/04/23 – 2015/04/24
Audit conducted on

調査範囲 (製品群) : As per attachment
Audit scope
(Product categories)

調査報告書 : MYQMH1114064-721411666
Audit report No.

調査結果 : 適合 / Passed
Audit result

当社は、QMS 適合性調査実施資格のある審査員によって実施された、平成 16 年厚生労働省令 第 169 号（厚生労働省令 平成 26 年第 87 号により改正）のうち調査対象施設に適用される条項に対する調査結果をレビューしました。

この確認書単独では有効性を持ちません。詳細は調査報告書をご参照ください。

TÜV SÜD Japan confirms that the audit was performed by auditor(s) authorized to audit according Articles, which are applicable for the audited facility, in MHLW ordinance No. 169 in 2004 as amended by MHLW ordinance No.87 in 2014, and that the audit results were reviewed by TÜV SÜD Japan, Ltd. This letter is only valid if accompanied by the audit report. Please refer to the audit report for details.

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Date of issue

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テュフズードジャパン株式会社は、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律（昭和 35 年法律第 145 号）第 23 条の 6 第 1 項の規定により登録された認証機関である。

TÜV SÜD Japan Ltd. is a certification body registered by Ministry of Health, Labor and Welfare according to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (1960 law No. 145) Article 23-6 clause 1.



JMDN 37149002 Trocar guide rod, single use
JMDN 37839001 Passer, suture
JMDN 70425000 Suture set, not absorbable
JMDN 32833000 Prosthesis, internal, joint, knee, unicondylar
JMDN 32836000 Prosthesis, internal, joint, knee, tibia, hemi
JMDN 35667000 Prosthesis, internal, joint, knee, total
JMDN 35668000 Prosthesis, internal, joint, knee, femoral component
JMDN 35669000 Prosthesis, internal, joint, knee, tibial component
JMDN 16077003 Fixation device, internal, bolt
JMDN 16101003 Fixation device, internal, screw
JMDN 32847003 Fixation device, internal, nut
JMDN 32854003 Fixation device, internal, pin
JMDN 33187000 Fixation device, internal, nail, intramedullary, femur
JMDN 34003000 Fixation device, internal, hip, plate, compression
JMDN 35241003 Fixation device, internal, plate
JMDN 35642004 Fixation device, internal, system
JMDN 35647003 Fixation device, external, system
JMDN 35685003 Fixation device, internal, wire
JMDN 36198003 Fixation device, internal, washer
JMDN 38152000 Fixation device, internal, nail, intramedullary, tibia
JMDN 38153000 Fixation device, internal, nail, intramedullary, humerus
JMDN 70502000 Fixation device, internal, bone, absorbable
JMDN 11332000 Drill, cannulated
JMDN 17507000 Bone tap
JMDN 35095000 Guide, surgical, drill bit
JMDN 11345000 Driver/extactor
JMDN 32390000 Drill bit, surgical
JMDN 32865000 Driver, prosthesis
JMDN 32871000 Wrench, surgical
JMDN 33968000 Screwdriver, surgical
JMDN 36235001 Drill, surgical, manual
JMDN 36235002 Drill, surgical, manual, single use
JMDN 32845000 Gauge, depth
